Department of Neurobiology, Care Sciences and Society
Karolinska Institutet, Stockholm, Sweden

IDENTIFICATION AND TREATMENT OF BACK PAIN IN ELDERLY WOMEN WITH OSTEOPOROSIS

Christina Kaijser Alin

Stockholm 2020

All previously published papers were reproduced with permission from the publisher.
Published by Karolinska Institutet.
Printed by US-AB Tryckeriet

ISBN 978-91-8016-000-1

IDENTIFICATION AND TREATMENT OF BACK PAIN IN ELDERLY WOMEN WITH OSTEOPOROSIS
THESIS FOR DOCTORAL DEGREE (Ph.D.)

By

Christina Kaijser Alin

Principal Supervisor:
Associate Professor Helena Salminen, MD
Karolinska Institutet
Department of Neurobiology, Care Sciences and Society
Division of Family Medicine and Primary Care

Co-supervisor:
Ann-Charlotte Grahn Kronhed, PhD, RPT
Linköping University
Department of Health, Medicine and Caring Sciences
Division of Prevention, Rehabilitation and Community Medicine

Title Name
University
Department of Fill in
Division of Fill in

Opponent:
Anna Holmberg, MD, PhD
Lund University
Department of Orthopedics
Division of Clinical and Molecular Osteoporosis Research

Examination Board:
Associate Professor Karin Hellström, RPT
Uppsala University
Department of Neuroscience
Division of Physiotherapy

Associate Professor Elisabeth Rydwik, RPT
Karolinska Institutet
Department of Neurobiology, Care Sciences and Society
Division of Physiotherapy

Professor Lars Borgquist, MD
Linköping University
Department of Health, Medicine and Caring Sciences
Division of Prevention Rehabilitation and Community Medicine

” All the flowers of tomorrow are hidden in the seeds that are sown today”

Chinese proverb

ABSTRACT

Older women with osteoporosis and back pain are common patients in primary health care. Varied physical exercise with focus on back extensor strength and balance is an important non-pharmacological treatment method that these patients can benefit from.
Aim: The overall aim of this thesis was to gain knowledge about complementary treatment methods of back pain in older women with osteoporosis with or without vertebral fractures in primary health care.
Material and Methods: Study I, a cross-sectional study, studied the relationship between spinal curvature and balance in a cohort of 96 women, 81-91 years old. Study II was an Randomised Controlled Trial (RCT) with 113 women ≥60 years, randomized to treatment with an activating spinal orthosis, to equipment training and to a control group during a treatment period of six months. Study III was a qualitative study in which 18 women were interviewed in five focus groups about their perceptions and experiences of using the activating spinal orthosis. Study IV was a post-intervention follow up study of the spinal orthosis group (n=38) and the exercise group (n=38) six months after the end of the RCT. We investigated how back pain, back extensor strength and other outcomes were affected when the participants used the spinal orthosis and the home exercise programme voluntarily.
Results: Study I: It was found that 31% of the women had suffered a vertebral fracture. Women with hyperkyphosis (n=45) had a better ability to tandem standing with eyes open, tandem gait forwards and tandem gait backwards. The age-adjusted Odds ratio (OR) to perform tandem gait (cut-off at four steps) for women with hyperkyphosis were for tandem gait forward OR 2.8 (CI 95% 1.1-7.4) and tandem gait backwards, compared to women without hyperkyphosis. Study II: Analysis between the activating spinal orthosis group, the training group, and the control group showed neither significant difference in back extensor strength nor in back pain, after six months of intervention. Women who had been treated with the activating spinal orthosis had insignificantly increased their back extensor strength with 27% (from 64.4 N to 81.7 N, p = 0.053) after six months of treatment. Women in the equipment training group increased their back extensor strength by 22% (from 59.6 N to 72.8 N, p = 0.013). Perceived back pain measured with VAS and Borg CR-10 showed no significant change in any group at the end of the RCT. Study III: The overall theme was "A well-adapted spinal orthosis could develop into a long-lasting friendship that provided support and help in daily life." Study IV: Independent use of the activating spinal orthosis and independent training, did not change previously obtained results in back extensor strength or other variables that were examined.
Conclusion: The results of the thesis indicate that the activating spinal orthosis could be used as an aid and as a training method for individuals with osteoporosis and back pain. However, physical training that involves and improves several functions of the body should be considered as the first-hand choice.

LIST OF SCIENTIFIC PAPERS

I. Kaijser Alin C, Grahn Kronhed A-C, Salminen H.

The association between spinal curvature and balance in elderly women at high risk of osteoporotic fractures in primary health care.
European Journal of Physiotherapy 2016:18(4):226-32.
dx.doi.org/10.1080/21679169.2016.1185151

II. Kaijser Alin C, Grahn Kronhed A-C, Uzunel E, Alinaghizadeh H, Salminen H

Effect of treatment on back pain and back extensor strength with a spinal orthosis in older women with osteoporosis: a randomized controlled trial.
Archives of Osteoporosis (2019) 14:5
https://doi.org/10.1007/s11657-018-0555-0

III. Kaijser Alin C, Frisendahl N, Grahn Kronhed A-C, Salminen H

Experiences of using an activating spinal orthosis in women with osteoporosis and back pain in primary care.
Archives of Osteoporosis (Accepted for publication 2020-05-07)

IV. Kaijser Alin C,. Grahn Kronhed A-C, Uzunel E, Salminen H

Wearing an activating spinal orthosis and physical training in women with osteoporosis and back pain – a post-intervention follow-up study. (Manuscript)

LIST OF ABBREVIATIONS

BMD	Bone Mineral Density
Borg CR-10	Borg Categoric Rate - 10
DFRI	Downton Fall Risk Index
DXA	Dual-energy X-ray Absorptiometry
EQ-5D	EuroQol Five Dimensions Questionnaire
FES	Falls Efficacy Scale
PBM	Peak Bone Mass
PRIMOS	Primary Health Care and Osteoporosis
QUALEFFO	Quality of Life Questionnaire of the European Foundation for Osteoporosis
RCT	Randomised Controlled Study
SD	Standard Deviation
SF-36	Short Form Health Survey 36
TBI	Total Back Index
VAS	Visual Analogue Scale

INNEHÅLLSFÖRTECKNING

1 INTRODUCTION

Osteoporosis and fragility fractures are a major health problem among older people [1]. A fragility fracture can cause severe pain in the acute phase, and at later stages it may cause chronic pain and difficulties in performing daily activities. The burden of fragility fractures leads to increased healthcare costs for medical treatment and rehabilitation in addition to the suffering of the patient caused by the fracture [2].

1.1 DEFINITION

Osteoporosis is characterized by decreased bone density and an increased risk of fractures. According to the WHO, osteoporosis is defined as “a systemic skeletal disease characterized by low bone mass and micro architectural deterioration of bone tissue, leading to enhanced bone fragility and a consequent increase in fracture risk” [1] WHO 1994. The definition of osteoporosis is based on the BMD (Bone Mineral Density) measurement expressed in T-scores [1]. The value of the BMD is compared to a reference population of young individuals of the same sex and ethnicity who have reached their PBM (Peak Bone Mass), which occurs between 25 and 30 years of age. The T-score is used in the clinical context as a diagnostic criterion for osteoporosis. It shows the number of SDs (Standard Deviations) that the patient's value deviates from the PBM (Peak Bone Mass). Diagnostic criteria for osteopenia, osteoporosis, and manifest osteoporosis apply to T-scores from DXA (Dual-energy X-ray Absorptiometry) measurement at the lumbar spine and hip.

Normal bone density	T-score ≥ –1 SD of a reference population of young individuals
Osteopenia	T-score < –1 and > –2.5 SD
Osteoporosis	T-score ≤ –2.5 SD
Established osteoporosis	T-score ≤ –2.5 SD and a fragility fracture [3].

The cut-off points above are valid for postmenopausal women. Cut-off points for younger individuals and for men are missing. In clinical practice, the same cut-off points are used for men and women. Sweden is one of the countries with the highest incidences of fragility fractures in the world, and the lifetime risk for a Swedish woman who is 50 years old to suffer a fragility fracture is 47.3% and the lifetime risk for a Swedish man is 23.8% [4]. Vertebral fractures are the most common fragility fracture and hip fracture is the most serious fragility fracture and can cause severe complications with long rehabilitation and difficulties in returning to daily activities. About 20% of patients who suffer a hip fracture die within a year of the injury [5].

1.2 VERTEBRAL FRACTURES

Osteoporosis and back pain with vertebral fractures is a common condition in older women that often leads to visits to primary care. Vertebral fractures are the most common type of fragility fracture [6]. A vertebral fracture that occurs suddenly can be very painful in the acute phase. In the aftermath, a vertebral fracture can lead to chronic pain conditions due to changed load conditions of the back. A vertebral fracture can also occur gradually over a longer period without symptoms of back pain. The symptoms in the back may arise gradually as fatigue pain as well as impaired posture and the development of kyphosis, loss of height, and impaired lung function, especially in the case of multiple vertebral fractures. Underdiagnosis of vertebral fractures is a major problem, and it is estimated that only one third of all vertebral fractures are detected clinically [7]. A vertebral fracture is often located in the area around the thoraco-lumbar transition, but can occur throughout the thoracic spine and lumbar spine. Back pain and impaired posture often occur as a result of a vertebral fracture, which can affect important daily activities and can lead to impaired health-related quality of life (HRQL) [8-10]. The diagnosis of vertebral fractures is made by a radiograph of the thoracic and lumbar spine and can be classified according to Genant´s "Semiquantitative Grading for Vertebral Fractures" [11]. When classifying fractures according to Genant, the height of the vertebra and the location of the compression are assessed, and if the height of the vertebra has decreased more than 20% a vertebral fracture is diagnosed [11]. After having experienced one vertebral fracture the relative risk to suffer another vertebral fracture is four times greater than those without prior fractures. Having several previous fractures further increases the risk [12,13]. Treatment with bone-specific drugs can prevent new vertebral fractures but has no effect on the back pain that can occur after a vertebral fracture.

1.3 SPINAL CURVATURE IN PATIENTS WITH OSTEOPOROSIS

1.3.1 Kyphosis

Increased thoracic kyphosis occurs frequently in women who have reached the age of 75 years or older [14]. In individuals with osteoporosis, thoracic kyphosis often occurs after multiple wedge-shaped vertebral fractures and can lead to increased mortality [15]. An association is also seen between osteoporosis-related fracture and BMD, previous fractures, and increased thoracic kyphosis [16]. Independent of osteoporosis, increased thoracic kyphosis is associated with an increased risk of falls and fractures [16,17] [17]. It has also been shown that osteoporotic kyphosis can lead to decreased lung function [18, 19, 20]. Several studies have shown that people with osteoporosis, with or without thoracic kyphosis, have impaired postural control and thus are at higher risk of falling and suffering a fracture [21, 22]. It is not clear whether impaired balance in individuals with thoracic kyphosis is due to weak back extensor muscles or to the thoracic kyphosis. Some studies have shown that patients with osteoporosis have impaired postural balance and that the problems become worse in patients with both osteoporosis and increased thoracic kyphosis [22]. Other studies have shown uncertain results when examining the association between impaired postural balance and osteoporosis, especially in younger postmenopausal women [23-25]. One study showed that vertebral fractures were associated with impaired balance independent of thoracic kyphosis [26].

1.3.2 Lumbar lordosis

Individuals with straightened lumbar lordosis and especially lumbar kyphosis have been shown in previous studies to have impaired balance and increased risk of falling regardless of the occurrence of thoracic kyphosis. However, no account was taken of whether the patient had one or more vertebral fractures [27,28].

1.4 TREATMENT WITH TRAINING OF BACK EXTENSOR MUSCLES

Several studies have shown that training of the back extensor muscles is an important part of the treatment of individuals with osteoporosis. Exercises that increase the strength of the back extensor muscles have been shown to reduce back pain and improve HRQL. It has also been shown that training of the back extensor muscles can positively affect balance and fear of falls and thus falls and fractures can be prevented [29, 30, 31, 32, 33, 32]. Training of back extensor muscles is an important part of the prevention of vertebral fractures, as has been shown in previous studies [33, 34]. With increasing age, the strength in back extensors muscles decreases, which can lead to the development of kyphosis. Training of the back extensor muscles can delay the progression of hyperkyphosis and improve posture [35].

1.5 TREATMENT WITH AN ACTIVATING SPINAL ORTHOSIS

An activating spinal orthosis has been developed that activates the back extensor muscles and at the same time stabilizes the back. This activating spinal orthosis has been studied in rehabilitation after an acute vertebral fracture and in previous studies it was shown that back pain significantly decreased and daily activities were facilitated [36, 37]. Treatment with an activating spinal orthosis after a vertebral fracture in the subacute phase have in several studies shown to increase back extensor strength and reduce problems with back pain in individuals with osteoporosis, back pain and vertebral fractures [38, 39, 40]. The results of some studies also show that the spinal orthosis can improve a kyphotic angle, facilitate daily living as well as body sway [39, 40]. There is a lack of studies about treatment with an activating spinal orthosis in individuals with osteoporosis and back pain with or without vertebral fractures and more chronic symptoms with back pain. In one study it was shown that postmenopausal osteoporotic women with or without vertebral fractures significantly improved back extensor strength and back pain in the activating spinal orthosis group [41]. It has also been shown that gait speed and daily activities improved, while wearing an activating spinal orthosis for six months in women with osteoporosis, with or without vertebral fractures [42]. Studies that can confirm positive results that have emerged so far on treatment with an activating spinal orthosis are needed. An activating spinal orthosis could be a treatment option to strengthen the back extensor muscles and facilitate daily life for patients with osteoporosis and back pain in primary health care. Efforts are needed to reduce the number of vertebral fractures, improve and expand treatment methods and treatment options for individuals who have been diagnosed with osteoporosis and who have back pain that affect daily activities.

1.6 BALANCE

Balance control depends on several different systems in the body interacting; the musculoskeletal, neuromuscular, vestibular, somatosensory and visual systems [43]. With increasing age, the balance deteriorates due to degenerative changes in these systems. Muscle strength in the musculoskeletal system decreases significantly with the aging process.

Reduced muscle strength leads to increased fall and fracture risk in the elderly [44-46]. The ability to coordinate different muscle groups in balance-demanding situations also deteriorates with increasing age [47]. Physical training with strength training of back extensors muscles and trunk muscles is an effective treatment method that provides increased axial stability and the ability to find balance in demanding situations, which can prevent falls and fragility fractures [48]. In a previous study, it has been shown that individuals with osteoporosis show higher postural sway velocity than controls despite of other problems in the back [49]. Hyperkyphosis is a condition that can be seen in individuals with osteoporosis and can be caused by wedge-shaped vertebral fractures. In a study where the relationship between osteoporosis-related hyperkyphosis and balance was studied, it could be seen that in people with hyperkyphosis, balance and postural sway as well as the strength of the back extensors were significantly reduced [21]. Another study indicated that individuals with osteoporosis had greater postural sway compared to individual without osteoporosis. In individuals with kyphosis and osteoporosis, the postural sway increased more [50]. It has been shown that individuals with osteoporosis-related hyperkyphosis have decreased back extensor strength, increased body sway and gait unsteadiness that may increase the risk of falls [21]. Training of the back extensor strength plays an important role in order to improve axial stability and prevent falls and fragility fractures [51]. In a couple of studies where an activating spinal orthosis has been used it was shown that back extensor strength increased and that body sway was improved in patient with osteoporosis, back pain and atraumatic vertebral fractures [39,40,52].

2 OVERALL AIMS

The overall aim of this thesis was to gain knowledge about complementary treatment methods of back pain in older women with osteoporosis with or without vertebral fractures in primary health care.

2.1 SPECIFIC AIMS

The specific aims were

- to investigate the relationship between spinal curvature and balance in older women with an increased risk of osteoporotic fractures (Study I).

- to evaluate the effect of treatment with an activating spinal orthosis on back pain and back extensor strength in older women with osteoporosis and back pain compared to equipment training led by a physiotherapist and a control group over a treatment period of six months (Study II).

- to gain increased knowledge about the perceptions and experiences of using an activating spinal orthosis in women with osteoporosis and back pain (Study III).

- to investigate in a post-intervention follow-up study how back pain, back extensor strength, and other secondary outcomes were affected in the participants voluntarily using the activating spinal orthosis and training according to a home exercise programme over a six-month follow-up period (Study IV).

3 MATERIAL AND METHODS

3.1 STUDY DESIGN

Four different study designs were used in this thesis – a cross-sectional (Study I), a randomised controlled trial (RCT) (Study II), a qualitative study with focus group interviews (Study III), and a post-intervention follow-up study (Study IV). An overview of the study design, data collection, participants, and statistical analyses is given in Table 1.

Table 1. Overview showing the study design, data collection, participants, and statistical analyses of the studies included in this thesis.

Study design	Data collection	Participants	Statistical analyses
Study I Cross-sectional study	Individual visits Background questions EQ-5D Clinical tests Radiographs of the thoracic and lumbar spine	A cohort of 96 women, 81–91 years old, living in Bagarmossen, a suburb in Southern Stockholm	Descriptive and comparative statistical analyses. Logistic regression analyses were used for calculation of odds ratios
Study II Randomised controlled trial	Individual visits Background questions EQ-5D Clinical tests Radiographs of the thoracic and lumbar spine	Participants came from three different sources; - *participants in study I (n = 13)* - *participants in an Osteoporosis School (n = 15)* – *participants responding to advertisement in local newspapers (n = 85)* Randomised (n = 113)	Descriptive and comparative statistical analyses. Mixed linear model analyses according to intention to treat.
Study III Qualitative study	Focus-group interviews	A group of 18 women who had used the activating spinal orthosis Spinomed	Qualitative content analysis with an inductive approach.
Study IV Follow-up six months after the end of the interventions in the randomised controlled trial (Study II)	Individual visits Background questions EQ-5D Clinical tests	A group of 76 women who participated in Study II *Spinal orthosis group (n = 38)* *Exercise group (n = 38)*	Descriptive and comparative statistical analyses.

3.2 THE STUDY POPULATION

The women who participated in the four studies of this thesis came from three different sources.

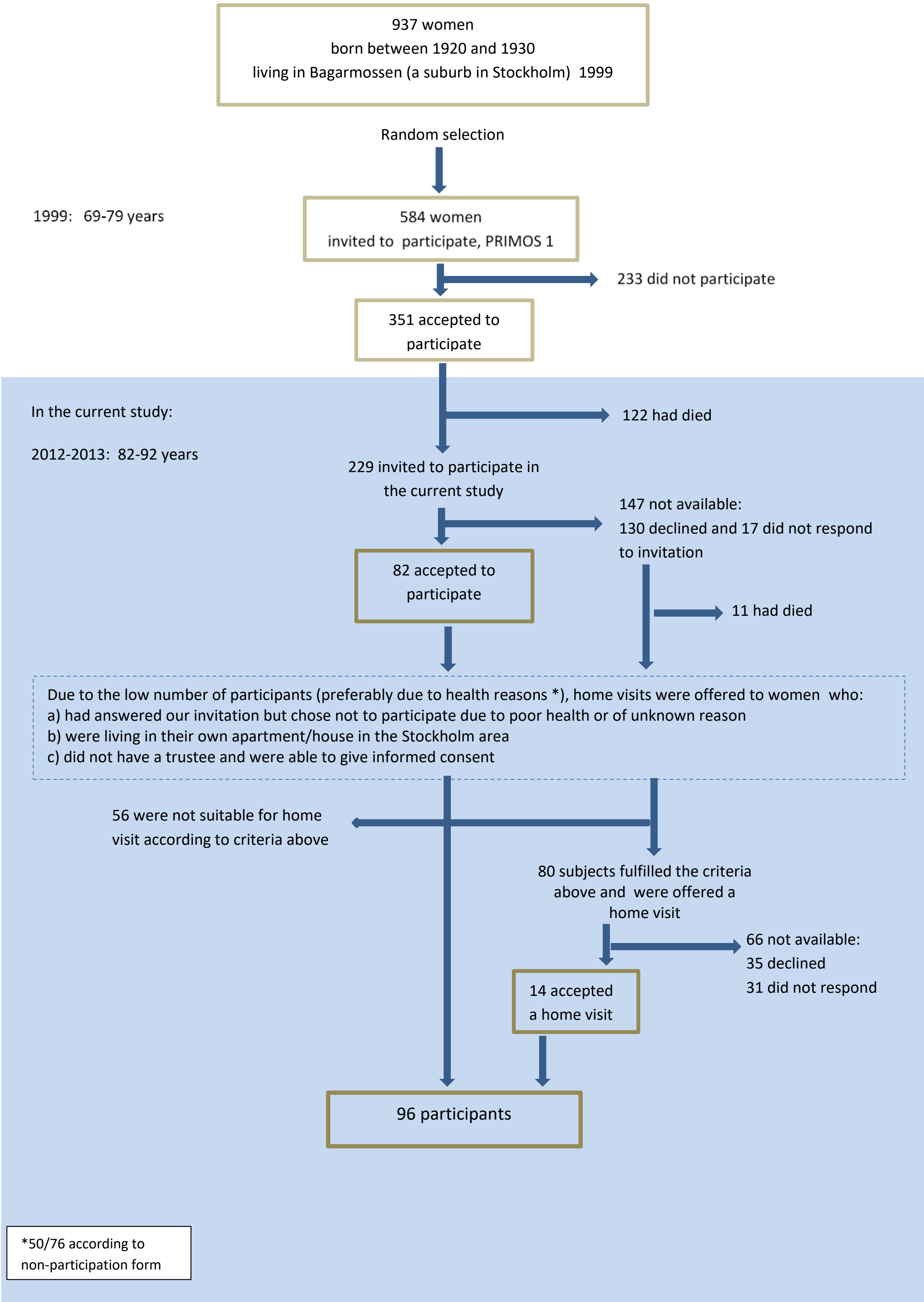
3.2.1 Study I

The population in study I consisted of 96 women born between 1920 and 1930 who lived in Bagarmossen, a suburb in Southern Stockholm. They had previously participated in the research project PRIMOS (Primary Health Care and Osteoporosis Study) between 1999 and 2000, which is when baseline data were collected [53, 54, 55]. Originally there were 937 women included in the cohort, of which 351 accepted to participate in the PRIMOS project. Study I was started in 2011, and 229 women were invited to participate. Out of the 351 women who participated in PRIMOS, 122 women had died between 2000 and 2011. This cohort of women had become very old, ranging in age from 82 to 92 years. The flowchart of study I is given in figure 1.

3.2.2 Non-participation and drop-out analyses, Study I

Due to old age and reduced functional ability and difficulties in getting to the examinations, 130 women declined to participate in Study I and 17 women did not respond. Eleven of these 17 women had died. There were only 82 women who accepted to participate, and because of the low number of participants home visits were offered to 130 women who had declined participation due to poor health. To be met for a home visit, the woman had to have refused to participate mainly due to poor health, had to live in her own accommodation, and had to be able to give informed consent. Of the 130 women, 50 women did not meet the criteria or did not respond to the invitation to a home visit, while 80 women met the criteria and were invited for a home visit. Of these, 35 women declined continued participation, 31 women did not respond to the invitation, and 14 women accepted a home visit. For the 35 women who responded but declined further participation, a drop out analysis was performed via a telephone interview in which 30 women were interviewed. According to the interviews, 63% abstained due to poor health and 37% out of disinterest in further participation. The interviews also showed that the women who refused further participation to a greater extent were living alone, 80% compared to 65% for those who participated. More non-participating women (57%) used walking aids compared to the study participants (38%). Home care and home health care were used by slightly more women among the non-participants. Otherwise, there were no noticeable differences between those who abstained and those who participated.

Figure 1. Flowchart of the study population - Study I



3.2.3 Study II

The participants included in Study II came from three different sources.
Inclusion criteria were diagnosed osteoporosis, back pain with or without vertebral fractures, and being a woman aged $\geq$60 years. Exclusion criteria were difficulties in following the research protocol, spinal stenosis, and language problems.
An invitation was sent to the 82 women included in Study I who were not offered a home visit, and 13 women met the criteria and accepted to participate. An invitation was also sent to 52 women who participated in an Osteoporosis School at Primärvårdsrehab Serafen 2007-2010, of which 15 women met the criteria and accepted to participate in this study. A request to participate in the study was published in four local newspapers and in the patient association's magazine. In this way, 85 additional participants were recruited. A total of 113 women were randomised to the three arms. The number of participants and drop-outs in Study II are shown in Figure 2.

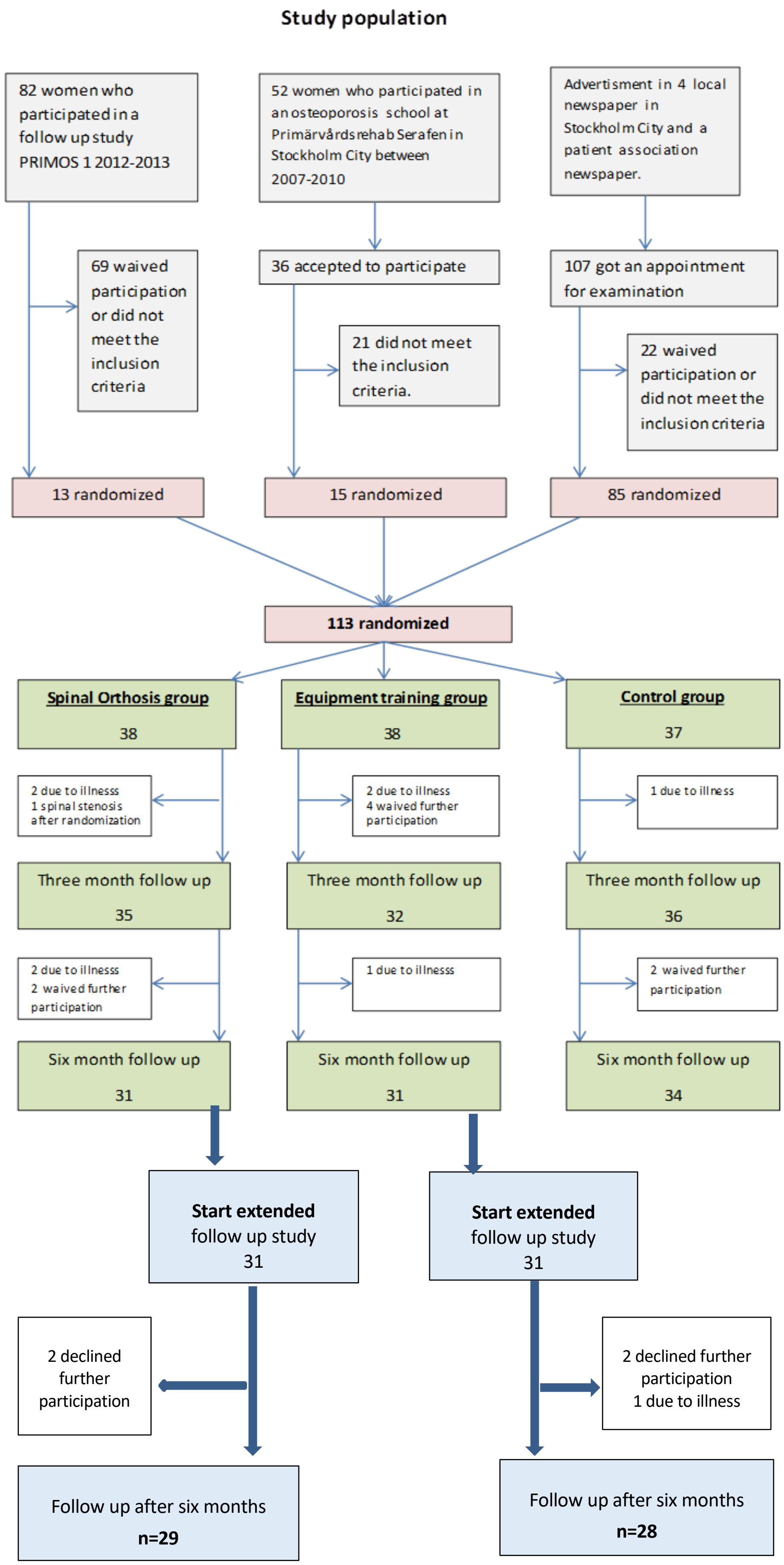
3.2.4 Study III

The 31 women who had been wearing the spinal orthosis for six months in Study II were invited to a qualitative study with focus-group interviews. Eighteen women accepted to participate, while 13 women declined participation due to conflicts with activities, holidays, poor health, or professional work.

3.2.5 Study IV

Those women who had completed the six-month intervention in the RCT, including 31 women in the spinal orthosis group and 31 women in the training group, were asked to come for a follow-up after another six months. The women were informed that they could wear the spinal orthosis and exercise completely voluntarily during the six months. In the spinal orthosis group, 29 women came for a follow-up visit and in the training group 28 women came for a follow-up. The number of participants in each group and the drop-outs are shown in Figure 2.

Figure 2 Flow chart for Studies II and IV



3.3 DATA COLLECTION

3.3.1 Study I

All data were collected during the visit to the physiotherapist or physician. The women were also referred for a radiograph of the thoracic and lumbar spine to determine whether they had vertebral fractures.

3.3.2 Study II

Study II was designed as an RCT, and data were collected on four occasions. The study was conducted from May 2012 to December 2014. At the first appointment, with a physiotherapist or a physician, all baseline data and measurements were collected, and women who met the inclusion criteria were randomised. All women who had not participated in Study I were referred for a radiograph to determine if they had suffered vertebral fractures. After one month, a letter was sent with questions about changes in medication and back pain. Visits two and three were appointments to a physiotherapist or a physician. The visits in the RCT are shown in Table 2.

Table 2. Flow chart of the visits in the RCT.

Baseline measurement	Visit 0	A letter	Visit 1	Visit 2	Visit 3
	Randomisation	One month	Three months	Six months (end of treatment)	12 months (follow-up)

3.3.3 Study III

Study III was a qualitative study with a qualitative inductive approach, and the data were collected through five focus-group interviews conducted from November 2014 to January 2015 [56, 57]. The focus-group interviews were performed by the author and an observer. The observer took notes about what happened during the interviews and about what could not be captured on the recordings. A semi-structured interview guide was used that contained several open-ended questions regarding thoughts about how the spinal orthosis affected the participants' daily life. Perceptions of how it felt to wear the spinal orthosis and thoughts about handling the orthosis were also expressed during the interviews.

3.3.4 Study IV

Study IV was a post-intervention follow-up study where the data collection was performed six months after the end of the RCT. The visits in Studies II and IV are shown in Table 2.

3.4 MEASUREMENTS

3.4.1 Back pain

In Studies I, II, and IV, back pain was assessed with a VAS (Visual Analogue Scale) where no pain was rated as 0 mm and the worst possible pain was rated as 100 mm and with the Borg CR-10 where no pain was rated as 0 and the worst possible pain as 10 [58, 59,60,61]. In Study II, back pain was the primary outcome and was assessed at baseline, after one month, at three months, and at the end of intervention after six months. Back pain was scored as present back pain as well as an overall assessment of pain during the previous week.

3.4.2 Muscle strength

In Study I, back extensor strength was measured by back raising (lying on the abdomen) with the arms at the sides with a maximum time of three minutes [62]. In Studies II and IV, back extensor strength was measured with the computerised device DigiMax (Mecha-Tronic, Germany) [38,39]. Participants sat in a fixed standardised position with a seatbelt around the hip and chest and with a 90° angle between the hip and knee. The participant pressed the upper part of the body against a plate for six seconds. The results were presented in Newtons (N) as the mean pressure for six seconds and as the maximum pressure at any time during the six seconds. Grip strength for both the right and left hand was measured with a Jamar dynamometer.

3.4.3 Spinal curvature

In Studies I, II, and IV, the spinal curvature was measured with a Flexicurve ruler (manufacturer Pedihealth AB). The Flexicurve ruler is flexible and is moulded to the curve of the spine with the patient in as upright a position as possible, and then the curve of the ruler is traced on paper [63,64]. The instrument has been suggested to be reliable and valid compared to other non-invasive methods for measuring spinal curvature. In Study II, the spinal curvature was measured at baseline and then six months later at the end of the study.

3.4.4 Balance and gait speed

In Studies I, II, and IV, both static and dynamic balance tests were performed. The static tests included the following three tests. Standing test on two legs was performed with the feet close together and the arms crossed in front of the body with the eyes open and with the eyes closed. In the tandem standing balance test, one foot was placed in front of the other (heel to toe on a line) with the eyes open and with the eyes closed. The one-leg standing balance test was performed on each leg with the eyes open and the eyes closed and the arms in front of the body and no support for the lifted leg. The static balance tests were performed without shoes and were each performed twice. The time of the test was limited to a maximum of 30 s, and if the supporting foot was moved or the arms or the lifted leg touched any support the timing was stopped.

The dynamic balance tests included the tandem gait forwards heel to toe on a line and the tandem gait backwards toe to heel between two lines with 15 cm between the lines. The tests were performed twice in each direction with a maximum of 15 correct steps and were stopped in case of a wrong step. All participants were given two attempts to perform the tests [65, 66]. In the timed gait speed test for 30 m, the participants wore shoes and walked as fast as possible for 15 m, turned, and walked back without losing their balance. The participant was allowed to use a walking aid during the test when needed.

3.4.5 Pulmonary capacity

Spirometry (Welch Allyn, SpiroPerfect Spirometry, USA) was performed to assess forced vital capacity (FVC) in Studies I, II, and IV. In Study II, spirometry was measured at baseline, after three months, and at the end of the intervention after six months.

3.4.6 Tools and instruments for risk assessment

In Studies I, II, and IV, the risk of falling was assessed with the DFRI (Downton Fall Risk Index), and the EQ-5D (EuroQol Five Dimensions) questionnaire was used to assess self-rated perceived health [67, 68, 69].

In all four studies, the participating women answered a questionnaire that included questions about risk factors for osteoporosis and fragility fractures, including age, marital status, form of housing, home care, home health care, medications, calcium and vitamin-D supplementation, other diseases, use of walking aids, falls in the past year, fractures in adulthood, and type of fracture. Questions were also asked about physical activity, time spent outdoors ≥30 min per day, smoking, health status compared to peers, and ability to get up from a chair without support from the arms. Present height and weight were measured, and the participants were asked about their height as young adults.

3.4.7 Radiographs

In Studies I and II, all participants were referred at baseline for a radiograph of the thoracic and lumbar spine to determine whether there were any vertebral fractures.

3.5 INTERVENTION

In Study II, which was an RCT, the participants were randomised into three arms – the spinal orthosis group, the equipment training group, and a control group.

In the spinal orthosis group, the participants were instructed to wear the spinal orthosis at least two hours a day for six months and that they could divide the time wearing the spinal orthosis into shorter periods during the day.

The orthosis used in the study was the activating spinal orthosis Spinomed (Medi AB, Germany). It is constructed with a steel rail that runs along the back from the spinous of the seventh vertebra to the sacrum and is adapted to the spinal curvature. The rail is plugged into a compartment on the orthosis. There are straps around the shoulders, and these are fastened around the pelvis and provide support for the lumbar spine through the pressure that occurs when the orthosis is tightened. The orthosis is put on like a backpack. When the person flexes their back, the rail that is adapted to the spinal curvature and the straps around the shoulders will give feed-back to continuously activate the back extensor muscles. The participants had the orthosis adapted by an orthopaedic technician who adapted it to their back in as upright a position as possible.

The equipment training group trained once a week in a gym supervised by a physiotherapist. The exercise programme focused on strengthening the back extensor muscles and muscles in the legs, as well as on both static and dynamic balance performance. The participants were also given a home exercise programme to perform at least four times a week [29, 70,71, 72 ,73].

The control group received no intervention but was allowed to continue with their normal activities just as before.

3.6 DATA ANALYSES

3.6.1 Statistical methods

Group results were reported as means and standard deviations (SD) for normally distributed continuous variables and as medians with interquartile ranges (IQRs) for skewed distributions. Significance levels below 5% were considered significant.

Analysis between the groups: Student's t-test was used for comparisons between groups for normally distributed variables, and the Mann–Whitney U-test was used for variables with a skewed distribution in Studies I and IV.
One-way analysis of variance (ANOVA) was used for comparisons of differences in continuous variables between the three treatment groups at baseline in Study II. The chi-square test was used for comparisons between groups with categorical variables in Studies I and II.

Analysis of changes within the groups: A paired t-test was used to analyse changes in normally distributed variables. The Wilcoxon signed-rank test was used for variables with skewed distributions in Studies II and IV.

In Study I, Spearman rank-order correlation coefficients (r_s) were used to study correlations between the spinal curvature and balance tests. Logistic regression was used to calculate the odds ratio for the ability to manage tandem walking steps forwards and backwards as dichotomous outcomes (with a cut-off value at four or more steps) and the presence of hyperkyphosis as an explanatory variable.

In Study II, the outcomes were analysed using a mixed model for repeated measures according to the intention-to-treat procedure [74].

The statistical methods used in this thesis are listed in Table 3.

Table 3. Statistical methods used in this thesis.

Statistical methods	Study I	Study II	Study IV
Student´s t-test	x		x
Paired t-test		x	x
Mann-Whitney U-test	x		x
Wilcoxon signed rank test			x
Chi^2	x	x	
ANOVA		x	
Logistic regression	x		
Mixed Model for repeated measures		x	

3.6.2 Qualitative method

In Study III, we used qualitative content analysis and followed the process that applies to inductive qualitative content analysis [75, 56]. To obtain objective results and investigate whether our analysis and perception of the text differed, the author and two co-authors began with an analysis of the interviews. Meaning-bearing units with similar content were extracted from the text and classified, condensed, and coded to form subcategories and overarching categories. Further analysis was performed jointly by all four authors, who reviewed the subcategories and developed these into three overarching categories. Finally, an overall theme covering all three categories was developed. Credibility is a key concept in qualitative research based on the five concepts of validity, reliability, subjectivity, transferability, and authenticity [56,76-78] [75, 76] . To achieve validity, the selection, design, and method were described in detail. Reliability was increased through a large proportion of the work being performed jointly by two or more co-authors. To reduce subjectivity, the coding and categorising were performed by two authors and the analysis was then performed jointly by all co-authors. The results section was authored by two co-authors separately, and their texts were then compared and merged into a final version by the entire research team.

3.6.3 Statistical software

In Studies I and IV, the data were analysed using the STATA statistical software versions 11 and 14 (StataCorp LP, Texas, USA).
In Study II, the data were analysed using the STATA statistical software versions 11 and 14, the SAS software version 14 (SAS Institute, Cary, NC, USA).

3.7 ETHICAL CONSIDERATIONS

All four studies obtained ethical approval from the Ethical Review Board of Stockholm (Reg. no. 2011/142- 31/3). All women who agreed to participate received both oral and comprehensive written information about the purpose of the study. All women signed a written informed consent for participation, and participation was voluntary and could be terminated at any time. All data were treated in accordance with the Swedish Personal Data Act.

4 RESULTS

4.1 STUDY I

The women who participated in Study I were split into two groups depending on their spinal curvature – women with normal kyphosis or hyperkyphosis and women with lumbar lordosis or no lumbar lordosis/lumbar kyphosis.

4.1.1 Spinal curvature and vertebral fractures

In this cohort of 96 women, 74 women were examined with sagittal spinal radiographs of the thoracic and lumbar spine to determine the presence of vertebral fractures. It was found that 31% of the women had one or more vertebral fractures. There was a total of 19 thoracic and 17 lumbar vertebral fractures. The group of women with hyperkyphosis had 14 vertebral fractures, and nine women with normal kyphosis had at least one vertebral fracture.

4.1.2 Spinal curvature and balance

The spinal curvature was measured on 88 women. The comparison between the women with normal kyphosis and those with hyperkyphosis showed that women with hyperkyphosis had significantly longer tandem standing time with the eyes open ($p < 0.05$), tandem gait forwards ($p < 0.05$), and tandem gait backwards ($p < 0.01$) (Table 4).

Table 4. Descriptive characteristics of the participants split into spinal curvature subgroups, including age, height, height loss, BMI, DFRI score, and balance tests.

	Normal kyphosis M (SD), number	**Hyperkyphosis** M (SD), number	**p-value**	**No lumbar lordosis** M (SD), number	**Presence of lumbar lordosis** M (SD), number	***p*-value**
Age, years	85.1 (2.29) *n*=43	84.8 (2.23) *n*=45	0.572	85.2 (2.14) *n*=19	84.8 (2.25) *n*=68	0.531
Height, cm	158.8 (6.13) *n*=43	158.3 (5.76) *n*=45	0.790	156.5 (7.10) *n*=19	159.2 (5.45) *n*=68	0.123
Height loss, cm	5.6 (2.84) *n*=42	6.6 3.19) *n*=45	0.141	7.2 (2.97) *n*=19	5.6 (2.73) *n*=67	**0.023**
Weight, kg	65.1 (9.84) *n*=42	65.1 (10.97) *n*=45	0.997	62.7 (12.10) *n*=19	65.9 (9.86) *n*=67	0.259
BMI, kg/m^2	25.9 (3.94) *n*=42	25.9 (3.82) *n*=45	0.909	25.6 (4.49) *n*=19	26.0 (3.71) *n*=67	0.528
DFRI score	3.1 (1.6) *n*=40	2.8 (1.5) *n*=43	0.376	3.0 (1.9) *n*=19	2.9 (1.5) *n*=63	0.887
Two feet standing eyes closed, s	20.2 (10.5) *n*=36	24.8 (9.0) *n*=41	0.093	20.8 (12.0) *n*=16	23.1 (9.4) *n*=60	0.681
Tandem standing eyes open, s	12.7 (11.5) *n*=36	18.3 (12.3) *n*=40	**0.040**	14.1 (13.2) *n*=15	16.3 (11.9) *n*=60	0.491
Tandem standing eyes closed, s	4.0 (6.7) *n*=36	5.6 (6.7) *n*=40	0.059	6.0 (7.6) *n*=15	4.6 (6.5) *n*=60	0.368
One leg standing eyes open, s	5.0 (6.1) *n*=43	7.1 (6.9) *n*=45	0.145	4.1 (4.4) *n*=19	6.7 (7.0) *n*=68	0.178
One leg standning eyes closed, s	1.0 (1.2) *n*=36	1.7 (1.5) *n*=40	0.061	1.2 (1.2) *n*=15	1.4 (1.4) *n*=60	0.738
Gait speed, s	31.4 (17.9) *n*=35	29.3 (11.8) *n*=40	0.692	33.0 16.2) *n*=15	28.3 (11.1) *n*=59	0.463
Tandem gait forwards, steps	3.6 (3.9) *n*=36	5.2 (3.9) *n*=40	**0.037**	5.3 (4.7) *n*=15	4.2 (3.8) *n*=60	0.533
Tandem gait backwards, steps	4.1 (4.1) *n*=36	6.9 (4.7) *n*=40	**0.008**	5.6 (5.0) *n*=15	5.6 (4.6) *n*=60	0.953

The Mann–Whitney U-test was used for comparisons between groups for variables with a skewed distribution, Student's t-test was used for normally distributed variables, and the chi-squared test was used for categorical variables. *p*-values less than 0.05 are in bold.
DFRI (Downton Fall Risk Index), BMI (Body Mass Index)

Analysis of the ability to perform four or more tandem steps forwards and backwards showed that women with hyperkyphosis performed significantly better than women with normal kyphosis. Tandem steps backwards showed an age-adjusted Odds ratio 4.5 (95% CI 1.7−12) for women with hyperkyphosis compared to women with normal kyphosis while tandem steps forwards showed age adjusted Odds ratio 2.8 (95% CI 1.1–7.4) for the same group of women.

4.2 STUDY II

The primary outcome was back pain, and the secondary outcomes were back extensor strength and spinal curvature estimated with kyphotic index. Baseline characteristics showed no significant differences between the three arms except for present back pain according to the Borg CR-10, which was scored significantly higher in the spinal orthosis group. Estimation of back pain showed a wide range, and measurement of back extensor strength showed a large variance in the three groups. Baseline characteristics are shown in Table 5.

Table 5. Baseline characteristics of the 113 participants in the RCT.

	Spinomed n = 38	**Training n = 38**	**Control n = 37**	
Variable	Mean (SD)	Mean (SD)	Mean (SD)	p-value[c]
Present height (cm)	159.8 (7.6)	159.3 (7.6)	161.5 (6.9)	0.407
Height when young (cm)	166.2 (5.7)	165.6 (6.3)	167.6 (5.7)	0.303
Weight (kg)	64.7 (13.4)	60.3 (8.5)	66.1 11.6)	0.073
Back muscle extensor strength[a] (Newtons)	64.4 (32.8)	59.6 (30.8)	62.3 (25.2)	0.791
FVC [b] (litres)	2.7 (0.7)	2.6 (0.7)	2.7 (0.6)	0.727
Variable	Median (IQR)	Median (IQR)	Median (IQR)	p-value[c]
Age (years)	77.9 (68.0–83.4)	77.6 (67.3–84.1)	72.8 (67.5–78.2)	0.201
Visual Analogue Scale Back pain, recent (mm)	22 (10–40)	9 (1–30)	21 (10–45)	0.088
Visual Analogue Scale Back pain, last week (mm)	50 (28–69)	39 (0–52)	43 (20–61)	0.181
Borg CR-10 back pain recently	3 (1−3)	2 (0.5−3)	2 (1−3)	0.049
Borg CR-10 back pain last week	4 (2−7)	3 (2−4)	3 (3−5)	0.168
Variable	%	%	%	p-value[d]
Kyphotic index ≥13	51.4	50.0	56.8	0.826
Vertebral fractures	36.8	31.6	24.3	0.508
Vertebral fracture X-ray	47.1	46.0	38.2	0.725

[a] Spinomed n = 35, training n = 38, control n = 36 [b] FVC Forced Vital Capacity
[c] One-way ANOVA was used for comparisons of differences between the three treatment groups.
[d] Chi^2 test was used for categorical variables as percentages.

4.2.1 Back pain

Analyses of back pain within the groups showed no significant changes, and analyses between the spinal orthosis group, the equipment training group, and the control group showed no significant differences after six months of the intervention.

4.2.2 Back extensor strength

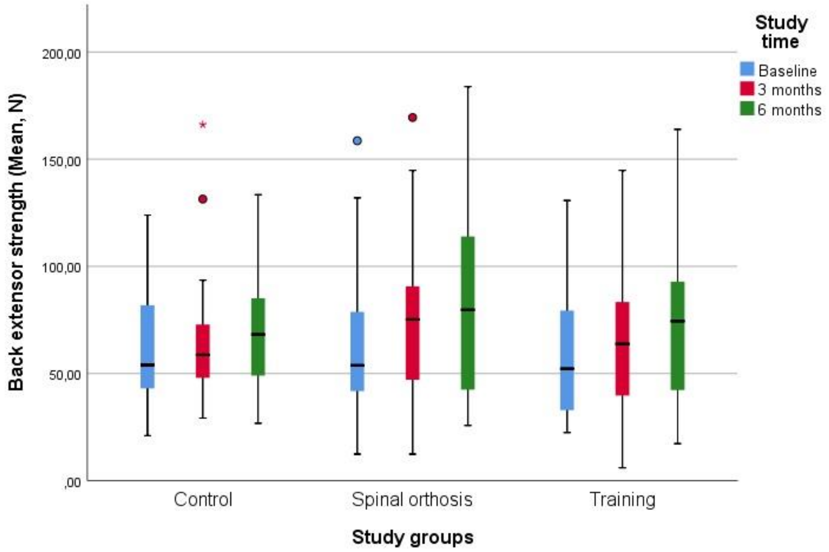
Analyses of the back extensor strength within the three groups showed that women who had been wearing the spinal orthosis had a statistically insignificant 27% increase in back extensor strength. Women in the equipment training group and training according to a home exercise programme showed a significant 22% increase in back extensor strength. In the control group, back extensor strength increased statistically insignificantly by 10% (Table 6).

Table 6. The change in percentage of back extensor strength in each group, as determined by paired t-tests. The analyses were per protocol.

		Baseline			Six months				
	Treatment group	**n**	**mean ± SD**	**95% CI**	**n**	**mean ± SD**	**95% CI**	**Change %**	**p-value**
Muscle	**Spinal orthosis**	25	64.4 ± 32.8	53.2 - 75.7	25	81.7 ± 41.3	65.4 - 98.0	26.9	0.053
Strength (N)	**Training**	30	59.6 ± 30.8	49.5 - 69.8	30	72.8 ± 37.3	58.9 - 86.8	22.1	0.013
	Control	31	62.3 ± 25.2	53.7 - 70.8	31	68.4 ± 27.0	58.7 - 78.1	9.9	0.153

Analyses of back extensor strength between the three arms were performed according to intention to treat (ITT) both unadjusted and adjusted for age, vertebral fractures, FVC, and examiner. After six months of the intervention, the back extensor strength showed no significant differences between the spinal orthosis group, the training group, and the control group (Figure 3).

Figure 3. Box-plots of back extensor strength separated into study groups and study time.



Contrast tests as a post hoc analyses were performed and showed no significant treatment effect. The effect size (f^2) could indicate a small treatment effect. Based on Cohen´s guidelines, the effect size was 0.09 [79] (Table 7).

Table 7. Changes in back pain and back extensor strength between groups at baseline and at follow-ups after three and six months, analysed according to intention to treat and by mixed linear models, showing the groups vs. time interaction with the LS mean ± SE, p-value, effect size, and power of the test adjusted for age, vertebral fractures, FVC, and examiner.

	Treatment group	**n**	**Baseline LS mean ± SE[b]**	**Three months LS mean ± SE[b]**	**Six months LS mean ± SE[b]**	**p-value**	**ES (f^2) [a]**	**Power [c]**
Back pain present VAS (mm)	**Spinal orthosis**	35	23.60 ± 4.07	20.00 ± 3.83	24.95 ± 3.93	<0.01	0.08	0.92
	Training	37	14.24 ± 3.81	14.09 ± 3.71	18.69 ± 3.76			
	Control	35	24.87 ± 4.14	27-65 ± 3.72	21.55 ± 3.69			
Back pain present Borg CR-10	**Spinal orthosis**	35	2.16 ± 0.29	1.96 ± 0.30	1.78 ± 0.30	<0.01	0.08	0.96
	Training	37	1.73 ± 0.27	1.36 ± 0.29	1.38 ± 0.28			
	Control	35	2.34 ± 0.28	2.36 ± 0.29	1.92 ± 0.28			
Muscle strength (N)	**Spinal orthosis**	35	65.89 ± 5.01	73.16 ± 5.15	82.48 ± 5.29	<0.01	0.09	0.99
	Training	38	60.66 ± 4.82	67.32 ± 5.01	74.86 ± 5.04			
	Control	36	58.93 ± 4.99	61.70 ± 5.12	65.41 ± 5.09			

p-value = interaction between time and treatment group.
[a] effect size (f^2) is based on Cohen's (1988) guidelines, $f^2 \geq 0.02$, $f^2 \geq 0.15$, and $f^2 \geq 0.35$ represent small, medium, and large effect sizes, respectively.
[b] estimated least square mean with SE (standard error) adjusted for age, vertebral fractures, and lung capacity.
The power of the test showed that the sample size was large enough to show a significant difference between the groups. Nevertheless, the contrast tests between the groups as a post hoc analysis showed no significant treatment effect.

4.2.3 Spinal curvature

Measurement of the spinal curvature showed no significant difference between the three treatment groups after six months of the intervention.

4.3 STUDY III

Qualitative content analysis of the interviews resulted in an overall theme, three main categories, and 13 subcategories. An overview of the overall theme, the main categories, and the subcategories is given in Table 8.

Table 8. Overall theme and the three main categories with their subcategories

Theme: **"A well-adapted spinal orthosis could develop into a long-lasting friendship that provided support and help in daily life"**	
Main category	**Subcategory**
Impact on daily life	Better posture Support Stronger back Pain relief Training equipment More reliable body control
Individual adaptation	Fitting Self-adjustment
Personal relationship	Expectations Notions of the orthosis Relationship over time Thoughts of the individual and reactions from those around them Thoughts about continuing use of the orthosis

4.3.1 Over all theme

A summary of the results that emerged in Study III was described in an overall theme. "*A well-adapted spinal orthosis could develop into a long-lasting friendship that provided support and help in daily life."*

The spinal orthosis could make daily activities easier to perform because the spinal orthosis provided support and the symptoms decreased. The positive effect was dependent on the spinal orthosis being well adapted to the back and fitting well. The relationship to the spinal orthosis could develop into a kind of friendship that could provide help in daily life. If the spinal orthosis was not experienced positively and did not provide help in daily life, no "friendship" was developed.

4.3.2 Main categories

The three main categories were*; Impact on daily life, Individual adaptation, and Personal relationship*

4.3.2.1 "Impact on daily life"

The respondents described how the spinal orthosis had increased their awareness of their back. It had improved their posture and it felt easier to breathe, and they could perform activities for longer periods, for example, taking long walks, which previously had been difficult. The respondents described that it was easier to travel on public transport because they felt safe and stable in their back. The spinal orthosis was perceived as a reminder not to perform movements that should be avoided. Several women described how their back pain had been toned down or disappeared, which made it easier to perform daily activities. The respondents described how they felt stronger in the back and that the orthosis could be an aid to start training and developing good exercise habits.

A woman expressed the following*; "I'm happy that I've grown so much stronger and can now do so much more than I've been able to over the last 20 years. I've been able to work for much longer periods both inside my home and out in my garden. And I'm now able to swim 500 meters compared to 100 meters before and I am also able to carry more. So, I think it had a very positive effect on my strength and posture."*

4.3.2.2 "Individual adaptation"

The respondents described how it was important that the orthosis was adapted individually and followed the spinal curvature and felt comfortable to wear. Good communication between the respondents and the orthopaedic technician during the adaptation of the spinal orthosis was important. It was also important to give detailed information about how the spinal orthosis should be handled. Some respondents stated that it was difficult to get the spinal orthosis to fit properly. Several respondents described how the spinal orthosis tended to ride up when they moved around and that they had to open it, pull it down, and button it again. Several respondents stated that the spinal orthosis had a strange shape that affected their appearance, and therefore they chose to hide it with a jacket or a sweater.
A woman said*: "I used it a lot when I was taking a stroll, etc. I had to move my body in many different directions and keep pulling the spinal orthosis down all the time".*

4.3.2.3 "Personal relationship"

The respondents described their expectations when they received a spinal orthosis and how they developed a relationship to the spinal orthosis over time. Several respondents described how the spinal orthosis was an aid to strengthening their back muscles and made their backs straighter and reduced back pain. Some respondents hoped it would be a turning point in their lives and would provide support for their back.

A number of respondents described how they developed a personal relationship with the spinal orthosis after they had been wearing it for some time and that they experienced some form of positive effect. The respondents who experienced that the spinal orthosis facilitated daily life intended to continue wearing it. Few respondents stated that they did not intend to continue to wear it because they still had back problems and because the spinal orthosis was difficult to take on and off.
A woman said: *“I have positive feelings about the corset. It’s like a good friend that you can take out either before you need it or when you start to feel fatigue in your back. So you know it’s there and it feels very positive”.*

4.4 STUDY IV

Analyses between the spinal orthosis group and the training group showed no significant difference for any variable after six months of voluntarily wearing the spinal orthosis and training according to a home exercise programme and in a gym.

Analyses within the spinal orthosis group and the training group showed no significant change for any variable at the six-month post-intervention follow-up. The test results measured at the end of the RCT were maintained in this post-intervention follow-up study.

Table 9. Changes within the spinal orthosis group and the training group from start to the end of the post-intervention follow-up study. Difference between the spinal orthosis group and the training group at the end of the follow-up study. Analysed per protocol.

	Spinal orthosis group n=29		Training group n=28		Change within groups[1]		Difference between groups[3]
	Six months	Start	Start	Six months	Spinal orthosis	Training	Spinal orthosis - Training
Variable	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**	**MD (95% CI)**
Back extensor strength mean n=26 (N)	85.2 (42.6)	79.8 (40.8)	76.2 (37.0)	77.2 (32.5)	5.4 (27.8)	0.96 (20.8)	3.3 (-16.9−23.5)
Back extensor strength max n=26 (N)	98.8 (47.9)	91.2 (45.8)	91.3 (43.9)	89.9 (36.7)	7.6 (31.6)	-1.4 (27.5)	3.2 (-19.5−26)
Gait speed 30 m (sec)	24.8 (11.4)	26.5 (11.5)	23.2 (6.1)	22.4 (7.2)	-1.1 (4.4)	-1.0 (3.5)	2.5 (-2.5−7.5)
Variable	**Median (IQR)**	**Median (IQR)**	**Median (IQR)**	**Median (IQR)**	**Median[2]**	**Median[2]**	**Median**
One leg standing right, eyes open (sec)	4 (2−30)	4.5 (2.5−20.5)	14.5 (5−30)	20 (3−30)	-0.5	6	-16
One leg standing left, eyes open (sec)	6.5 (2−25.5)	4 (2−11.5)	19.5 5.5−30)	15 (3−30)	2.5	-4.5	-8.5
Visual Analogue Scale back pain, recent (mm)	2 (0−33)	9.5 (0−52.5)	8.5 (0−36)	11 (0−20)	-7.5	2.5	-9
Visual Analogue Scale back pain, last week	35 (25−64)	35 (16.5−58.5)	30 (19.5−41.5)	35 (18−41)	0	5	0
Borg CR-10 back pain, recent	1 (0−2)	1.5 (0−3)	1 (0−2)	1 (0−2)	-0.5	0	0
Borg CR-10 back pain, last week	3 (3−3)	3 (2−3.5)	3 (2−3.3)	3 (2−3)	0	0	0

[1]The paired t-test was used for analysis of differences within the groups with normally distributed data. [2]The Wilcoxon signed rank test was used for analysis of data with skewed distribution. [3]Student’s t-test was used for analysis of difference between groups with normally distributed data. Analysis within groups and between groups showed no significant differences.

5 DISCUSSION

Back pain is a common problem in older women with osteoporosis, and this can adversely affect daily activities and is often a reason for visits to primary care. The overall aim of this thesis was to gain knowledge about treatment methods and treatment options that can facilitate daily activities in older women with osteoporosis and back pain with or without vertebral fractures.

5.1 MAIN FINDINGS

One of the main findings in this thesis was that the activating spinal orthosis might be an alternative treatment method and might reduce symptoms of the back and facilitate daily activities for women with osteoporosis and back pain. Women who wore the spinal orthosis increased the strength of their back extensor muscles close to statistical significance, but no significant difference was seen between the two treatment groups and the control group. Training in a supervised equipment training group combined with a home exercise programme was effective in obtaining increased back extensor strength. Another main finding was that women who felt that the activating spinal orthosis facilitated their everyday life and that it was well adapted to their back continued to use it after the end of the RCT. The spinal orthosis could be experienced both as an aid and as a training tool.

In this thesis, a cohort of 96 older women, were examined regarding vertebral fractures, kyphosis, and balance. The main findings were that about one third of the women had suffered one or several vertebral fractures and about half of the women had developed hyperkyphosis. The ability to perform tandem walking, both backwards and forwards, and tandem standing with the eyes open were better in women with hyperkyphosis, which was somewhat surprising.

5.2 VERTEBRAL FRACTURES

The most common fragility fracture is a vertebral fracture, and several studies have shown that many vertebral fractures go undiagnosed [80, 81, 82]. This underdiagnosis of vertebral fractures is a significant health problem for older individuals. In Study I, it was shown that one third of the women who had chosen to participate in the study had one or several vertebral fractures. These women were originally randomly selected from a normal population, and only three women had previously been diagnosed as having a vertebral fracture. In Study II, approximately 35% of the participating women with diagnosed osteoporosis stated that they had had a vertebral fracture, while radiographs of the thoracic and lumbar back showed that approximately 47% of the women had had a vertebral fracture. Our results regarding the underdiagnosing of vertebral fractures are in accordance with previous studies [80, 81, 82]. The diagnosis of vertebral fracture is often missed in primary health care. The patient might not be referred for a radiograph and then, even if a vertebral fracture is diagnosed, the patient rarely gets further assessment and treatment for osteoporosis. How vertebral fractures are described by radiologists in their responses might also cause problems, and sometimes the descriptions of vertebral fractures are so vague that the physicians do not completely understand the meaning of the findings [82]. Older vertebral fractures can also be asymptomatic or give only mild symptoms, and these patients are rarely referred for a radiograph. The findings in Studies I and II imply that there is a need for increased knowledge in primary health care as well as increased knowledge among radiologists for interpreting radiographs with suspected vertebral fractures [82]. This shows the importance of finding and giving these patients both pharmacological and non-pharmacological treatment that can prevent multiple future vertebral fractures, back pain, and impaired HRQL as well as prevent other fragility fractures [83]. It is of great interest to prevent new future vertebral fractures because after the first vertebral fracture, the relative risk of getting another vertebral fracture increases four times already during the first year after the first vertebral fracture [13]. Non-pharmacological treatment with training of the back extensor muscles has been shown to help to prevent vertebral fractures and improve HRQL [31, 72, 34, 84]. A referral to a physiotherapist who can develop individual exercise training programmes for patients with osteoporosis with and without vertebral fractures should be a routine measure in primary health care.

5.3 KYPHOSIS

Hyperkyphosis is often caused by several wedge-shaped vertebral fractures [85]. In Study I, all women were participants of a populations-based cohort with a long follow-up time and had radiographs of the thoracic and lumbar spine taken. It was found that half of the women had developed hyperkyphosis and that half of the women had one or several vertebral fractures [86]. This is in concordance with previous studies showing that hyperkyphosis is common in women over 75 years of age [85]. Hyperkyphosis is associated with previous wedge-shaped vertebral fractures because the risk of further vertebral fractures increases after the first fracture, and it has also been shown that there is an association between the individual’s BMD and hyperkyphosis [16]. Individuals visiting a primary health care centre who have developed hyperkyphosis should therefore be paid attention to as being at high risk of fragility fractures. Secondary fracture prevention can be initiated with bone-specific drugs that reduce the risk of another vertebral fracture [83]. Several studies have shown that hyperkyphosis is associated with an increased risk of falling [16, 17, 87], and decreased strength in the back muscles and lower extremities can be important for balance, body sway, and risk of falls [87]. Individuals with hyperkyphosis can therefore be offered fall and fracture prevention with training of the back and leg muscles as well as balance training. It has been shown that training the back extensor muscles with an activating spinal orthosis can prevent and positively affect hyperkyphosis and can decrease symptoms emanating from the back [88, 40]. However, in the studies for this thesis we did not see any improvement of the kyphosis after six months of training the back extensor muscles. One explanation for this might be that the kyphosis had been present for a long time. It can be difficult to influence kyphosis that has developed a long time ago because the structures around the vertebrae are not as flexible as before.

In Study I, the association between spinal curvature and balance was examined. In previous studies, it has been shown that individuals with hyperkyphosis and vertebral fractures more often have impaired postural control and have increased postural sway [87, 49, 89, 50.] . In Study I, we found a positive association between spinal curvature and the balance tests of tandem standing with the eyes open, tandem walking backwards, and tandem walking forwards in older women with osteoporosis. Women with hyperkyphosis performed these tests better than women with normal spinal curvature. Our results are supported by a study showing that individuals with thoracic kyphosis had better ability to perform tandem standing and tandem walking [90]. The better ability in the tandem tests can be explained by the fact that the thoracic kyphosis is compensated for by lumbar lordosis and pelvic tilting to move the "centre of pressure" backwards [91]. It has also been shown that strength in the muscles around the hip is of great importance for good results on the tandem standing test [92]. The muscle strength in the legs was not tested in Study I. Comparison of our results with other studies can be difficult because not all tests are performed in a similar way.

5.4 BACK PAIN

Individuals with osteoporosis often suffer from back pain. In this thesis, back pain was studied in older women with diagnosed osteoporosis in Studies II and IV, and back pain was the primary outcome. In many cases, back pain arises as a result of one or more vertebral fractures. The women in Studies II, III and IV suffered from chronic back pain and described the pain as a feeling of tiredness and aching in the back that occurred during, for example, standing work. According to several studies, a treatment method to relieve back pain in individuals with osteoporosis could be training of the back extensor muscles [29, 44,52,93]. Women who participated in Study II followed a training programme for six months with exercises to strengthen the back extensor muscles [94]. No significant difference was seen after six months of training concerning back pain [94]. One explanation might be the great variation in self-rated back pain at baseline. Several women rated their back pain quite low, and perhaps we should have been stricter in the inclusion criteria. It can be difficult to change chronic back pain from a relatively low level to a level with no pain at all.

5.5 NON-PHARMACOLOGICAL TREATMENT METHODS

Treatment with exercise and physical activity has been shown to be important for patients with osteoporosis. Balance training and increasing muscle strength have been shown to prevent falls and fragility fractures [29, 33, 34, 48.] Training and exercise have also been shown to improve functional ability such that daily activities are easier to perform and the individuals experience improved HRQL [29, 31, 72]. In this thesis we explored a complementary method of training the back extensor muscle for individuals with osteoporosis and back pain with an activating spinal orthosis compared to training according to an equipment training programme and a home exercise programme.

5.5.1 Back extensor strength

It has been shown in several studies that training of the back extensor muscles in individuals with osteoporosis can help to prevent vertebral fractures and relieve back pain [33,72]. Training of the back extensor muscles can also help to prevent falls and the development of hyperkyphosis and can facilitate an upright position of the back that provides a better posture [44,48,87].

5.5.1.1 Training according to an exercise programme

In Study II, individuals who had developed osteoporosis and back pain were offered training of the back extensor muscles as part of an equipment training group led by a physiotherapist. The training was individually tailored and was performed with an equipment training group once a week. The participating women also trained according to a home exercise programme at least four times a week. The training programmes focused on back extensor strength and its effects on pain as well as whether they could influence hyperkyphosis and improve posture. In addition to training with gym equipment, the women used rubber bands and Bobath balls and performed various balance exercises. After six months of training, the results showed a significant increase in back extensor strength (p = 0.013). One goal of increasing the strength in the back extensor muscles is to achieve secondary effects of decreased back pain, prevention of vertebral fractures, prevention of hyperkyphosis, and improved balance [95 33, 44,95, 48, 72]. The increased back extensor strength that could be seen after six months of exercise did not affect the kyphosis, and measurement with the Flexicurve ruler showed no change of the spinal curvature. We also investigated whether training of the back extensor muscle could reduce back pain. After six months of exercise, no statistically significant change could be seen in back pain. Although we did not get a significant improvement in back pain, it has been shown in several studies that strong back extensors reduce symptoms from the back and facilitate activities in everyday life and improve HRQL [29, 30, 31, 32]. Some participants in Study II rated their back pain as weak at baseline, which left little space for improvement. At the follow-ups, the participants stated that their back pain was slightly better, but not enough to give a statistically significant result. With the support of several studies, training of the back extensor muscles must be seen as an important treatment method for individuals with osteoporosis and back pain [44,52,84].

5.5.1.2 Training with an activating spinal orthosis

An activating spinal orthosis has been developed which, through its construction, activates the back extensor muscles while providing stability. In previous studies where the activating spinal orthosis has been used, it has been shown that the back extensor strength increased [39, 96, 97, 98]. In Study II, participants randomised to the spinal orthosis group were instructed to use the orthosis for at least two hours per day for six months. During the follow-up interviews, the participants had to state whether they used the spinal orthosis for the recommended two hours per day, which all participants had done. After six months treatment no statistically significant increase in back extensor strength was showed in the spinal orthosis group. In several studies where there was an increase in back extensor strength, patients had suffered vertebral fractures and individuals who used the activating spinal orthosis during their rehabilitation significantly improved their back extensor strength [38 40, 39]. The activating spinal orthosis is often initiated at a subacute stage after a vertebral fracture and part of the increase in back extensor strength might be due to a natural consequence of the healing process. The spinal orthosis is, at the same time, stabilising and also allows some mobility that continuously activates the back extensor muscles leading to increased back extensor strength [39]. Women included in Study II are a common group of patients visiting Primary health care. It is a heterogeneous group of individuals. There was a large range in age and a large variance in back extensor strength. The study population included women who suffered from vertebral fractures of older dates as well as women without vertebral fractures. It could be an explanation why the results showed no significant increase in back extensor strength and no decrease in back pain. The participating women had no problems with the severe pain that can occur after a vertebral fracture of more recent date. In comparison with the women who trained according to a group equipment training programme, combined with a home exercise programme and a control group, no significant difference in back extensor strength and back pain could be seen [94]. In our qualitative study, women who had a positive experience of the spinal orthosis described that it facilitated daily activities that previously had been difficult to perform. They also described that they felt stronger in their back and that their posture had improved. Some women described that the orthosis had not been of any help and this was mainly due to the fact that it did not feel comfortable to wear [99]. The results in this thesis indicate that an activating spinal orthosis can be used as a complement to back extensor training for individuals with osteoporosis and back pain visiting primary health care. However, physical training that involves and improves several functions of the body should be considered as the first-hand choice.

5.6 STRENGTHS AND LIMITATIONS

A strength of this thesis was that we performed a clinical trial and studied a common group of patients visiting primary health care. It was a study population that was very heterogenous. It can be a strength as positive results more easily can be generalized in the population but also a limitation as it may require many participants in order to get significant results. It is difficult to conduct clinical studies with older participants and it entails high costs. A strength of this thesis could be that a relatively new area with a lack of studied has been in focus.

In Study I, a cohort of women was chosen that has been followed since 1999, which can be seen as a strength because this makes it possible to continue research to see how different variables change over time in a longitudinal study design. What can be seen as a weakness in Study I is that the cohort studied is specifically women born within a 10-year period between 1920 and 1930 and who lived in the same area, which means that the results from this study cannot be generalised to a larger population at different ages and in geographically different areas. Since 1999 and until the start of Study I, a number of women had passed away, suffered from illness, or had considerably worse health, which led to a large number of drop-outs and a final study cohort of only 94 women, which is a small cohort. It can also be seen as a strength as the women who participated in this study can be seen as "survivors", and future studies will have the opportunity to investigate health factors.

The chosen study design of an RCT in Study II can be seen as a strength, where treatment results were studied in a wider group of women visiting primary health care with osteoporosis and back pain and with or without vertebral fractures. The treatment effect on back extensor strength and pain has been investigated in a number of studies, including patients with both acute and subacute vertebral fractures, but very little has been studied about the treatment effect on patients with osteoporosis and back pain only. It is also a strength of the study that the treatment effect was studied with a follow-up study, Study IV, six months after the end of the RCT. We wanted to study whether the investigated variables in Study II changed when the individuals were allowed to train completely independently without organised training from primary health care and when the participating women were allowed to use the spinal orthosis completely independently. We also wanted to gain knowledge about how the participating women in the spinal orthosis group experienced using the spinal orthosis. To get a comprehensive picture of how the spinal orthosis should be used, the participating women were invited to describe their experiences in a focus-group interview, which can be seen as a strength of this thesis.

One limitation of Study IV might be that the women might have had the feeling that they were participants in a controlled study because they had been asked if they wanted to come for a follow-up visit after another six months. This might have influenced the use of the spinal orthosis and following the exercise programme.

One limitation of Study II was that we could have chosen more specific inclusion criteria. There was a wide range in age because we did not have an upper age limit. Furthermore, a higher pain intensity on the VAS or Borg CR-10 could have been required to be included. In the inclusion criteria, there was no exact limit to how strong the pain should be experienced, only that the individual had symptoms of pain. Some individuals rated only 15–20 mm on the VAS and 2 (weak) on the Borg CR-10 at baseline, which might be an explanation for why no significant improvement in pain could be seen. Another limitation might be that four different examiners tested the participating women during the follow-up visits; for example, the person testing the participants might differ in how much they encouraged the participants to make as much effort as possible. Before starting the study, we went through exactly how each test should be performed, but there is a certain risk that the examiners did not perform the tests exactly the same way. For the equipment training group, it would have been optimal to exercise two to three times a week, but there was no practical opportunity to do so. The training was therefore performed once a week combined with a home training programme to be performed four times a week.

In Study III, focus-group interviews were chosen for data collection. A limitation might be that some respondents were hesitant to express their experiences in groups such that not all thoughts and experiences were reported. On the other hand, the respondents can might have stimulated each other and raised thoughts that were discussed further and developed, which might have provided a greater breadth and depth of views and might be considered a strength of the study.

5.7 CLINICAL IMPLICATIONS

The activating spinal orthosis could be an aid and a training method for individuals with osteoporosis and back pain who have difficulty to follow a training programme. For individuals with osteoporosis and back pain, comprehensive training of back extensor strength, balance, weight-bearing exercises for the skeleton and fitness are exercises that improve several functions in the body and can be seen as a first-hand choice. A patient with osteoporosis and back pain is often an older woman, but may also be a man, who may have developed other diseases and mobility impairments of various kinds. It requires that the training can be tailored individually and that there are alternative training methods to be offered. Several women who used the spinal orthosis and were satisfied with the orthosis have in focus group interviews described that they felt stronger in their backs, that their posture improved and that the spinal orthosis made it easier to perform daily activities that were previously difficult to perform. The women's descriptions show that an activating spinal orthosis, if it is fits well, facilitates everyday life. The activating spinal orthosis can be seen both as an aid that supports the back and as a training tool that activates the back extensor muscles.

5.8 CONCLUSIONS

The overall aim of this thesis was to gain knowledge about treatment methods and treatment options that can facilitate daily activities in older women with osteoporosis and back pain with or without vertebral fractures.

In this thesis older women with osteoporosis and back pain, with or without vertebral fractures and a cohort of older women that had been followed during about 15 years were studied. These women constitute a common group of patients in primary health care.

The results from this thesis confirm what previous studies have shown that vertebral fractures are underdiagnosed.

Treatment with an activating spinal orthosis compared with training in an equipment training group combined with a home exercise programme and a control group did not show any significant differences between the three groups in back pain or in back extensor strength. Training in the equipment training group combined with a home exercise programme significantly increased back extensor strength but in the activating spinal orthosis group no statistically significant increase in back extensor strength was shown after six months of intervention.

A qualitative study was performed where women who used the activating spinal orthosis described their experiences of the orthosis. It was found that the activating spinal orthosis could facilitate daily activities that were previously difficult to perform and that their back felt stronger. It was important that the orthosis was well fitted to the spinal curvature and felt comfortable to be accepted for continued use. The overall theme was: ”A well-adapted spinal orthosis could develop into a long-lasting friendship that provided support and help in daily life.”

In the post-intervention follow-up study it was shown that independent use of the activating spinal orthosis and independent training, without contact with primary health care for six months, did not change previously obtained results in back extensor strength or other variables that were examined.

The results in this thesis indicate that an activating spinal orthosis can be used as a complement to back extensor training for individuals with osteoporosis and back pain visiting primary health care. However, physical training that involves and improves several functions of the body should be considered as the first-hand choice.

6 FUTURE RESEARCH

The relationship between kyphosis, vertebral fractures, and balance has not been fully investigated and shows varying results. Balance is a complex system and is influenced by a number of factors. In future research, the entire back can be taken into account when studying how the spinal curvature affects balance and what kind of compensatory mechanisms are used to maintain balance. In Study I, a cohort of women was chosen that has been followed since 1999. This makes it possible to perform continued research to see how different variables change over time in a longitudinal study design.

Older women with osteoporosis and back pain, but also men, are visiting primary health care with symptoms of varying severity. In future research, it would be interesting to be able to identify the women and men who would benefit the most from wearing the activating spinal orthosis. It could also be interesting to study whether the spinal orthosis can have a positive treatment effect on balance. Physical activity and exercises as treatment methods for patients with osteoporosis and back pain are well investigated, but increased evidence for treatment with an activating spinal orthosis as a complementary treatment method is needed. In most studies the participants are older women. In future studies men should also be included to provide more comprehensive knowledge of the treatment effect of an activating spinal orthosis.

7 SAMMANFATTNING

En vanlig patientgrupp som söker primärvården är äldre kvinnor med osteoporos och ryggvärk. Osteoporos definieras enligt WHO som ”en systemisk skelettsjukdom karakteriserad av låg benmassa och en försämring av mikroarkitekturen i benvävnaden som leder till ökad benskörhet och ökad risk för fragilitetsfraktur”. Osteoporos upptäcks oftast när den första fragilitetsfrakturen har inträffat, vanligtvis i samband med ett fall, och blir ett bevis på att skelettet är skört. Sverige är ett av de länder i världen där flest fragilitetsfrakturer inträffar och livstidsrisken för en svensk kvinna som är 50 år att råka ut för en fragilitetsfraktur är 47,3% och för en svensk man 23,8%. Kotkompression är den vanligaste fragilitetsfrakturen och höftfraktur är en svår fragilitetsfraktur som kan orsaka allvarliga komplikationer med lång rehabiliteringstid och svårigheter att återgå till dagliga aktiviteter som tidigare. Cirka 20% av patienterna som råkat ut för en höftfraktur avlider inom loppet av ett år.
En kotkompression kan uppträda plötsligt och ge svår smärta men kan också utvecklas successivt över en längre tidsperiod utan att ge symtom. Symtomen kan komma gradvis med ökande trötthetsvärk, försämrad hållning och utveckling av kyfos samt längdminskning, speciellt vid flera kilformade kotkompressioner. Diagnosen kotkompression missas ofta vilket är ett stort problem. Enligt beräkningar så upptäcks endast en tredjedel kliniskt. Risken att råka ut för en ny kotkompression ökar betydligt efter den första. Den relativa risken att få ytterligare en kotkompression är fyra gånger högre än för de som inte råkat ut för en kotkompression tidigare. Patienter med osteoporos och fragilitetsfraktur skall erbjudas både farmakologisk och icke-farmakologisk behandling med målsättning att förebygga ytterligare fragilitetsfrakturer.

Hyperkyfos det vill säga ”kutrygg” är ett tillstånd som individer med osteoporos kan utveckla, ofta en följd av flera kilformade kotkompressioner och nedsatt ryggmuskelstyrka. Det finns samband med hyperkyfos, nedsatt postural kontroll och ökad risk för fall och frakturer samt att hyperkyfos i bröstryggen kan påverka lungkapaciteten negativt.

Träning av ryggmuskulaturen är en behandlingsmetod som personer med osteoporos och ryggvärk har stor nytta av. Hälsorelaterad livskvalitet (HRQL) kan förbättras, kotkompressioner kan förebyggas och den ryggvärk som personerna besväras av kan minska. Starka rygg- och bålmuskler förbättrar den axiala stabiliteten och underlättar att hitta balansen i utmanande situationer vilket kan förebygga fall och frakturer.

I syfte att förbättra och utöka behandlingmetoder som patienter med osteoporos och ryggvärk erhåller, har en aktiverande ryggortos utvecklats. Ryggortosen har använts och studerats både i rehabilitering efter en akut kotkompression och i det subakuta stadiet efter en kotkompression. Det visades att behandling med ryggortosen signifikant minskade ryggsmärta, ökade ryggmuskelstyrka och underlättade dagliga aktiviteter. Det finns få studier som studerat behandlingseffekten på individer med kroniska besvär av osteoporos och ryggvärk, med eller utan kotkompression. I ett par studier visades att behandling med den aktiverande ryggortosen gav starkare ryggmuskler och minskad ryggsmärta samt att gånghastigheten ökade och dagliga aktiviteter underlättades.

Varierad fysisk träning med stor vikt på ryggmuskelstyrka och balans är en icke-farmakologisk behandlingsmetod som individer med osteoporos och ryggvärk kan ha stor nytta av, vilket har varit fokus i detta avhandlingsarbete.

Syfte: Det övergripande syftet med denna avhandling var att få kunskap om kompletterande behandlingsmetoder av ryggsmärta hos äldre kvinnor med osteoporos, med eller utan kotkompression, som söker primärvården.

Metod och material: Studie I var en tvärsnittsstudie där vi undersökte sambandet mellan ryggradens kurvatur och balans samt förekomst av kotkompressioner i en kohort bestående av 96 kvinnor, i en ålder mellan 81 och 91 år. Kvinnorna hade tidigare deltagit i forskningsprojektet PRIMOS mellan 1999 och 2000 och var slumpvis valda ur en normalpopulation.

Studie II var en randomiserad kontrollerad studie (RCT), där 113 kvinnor deltog i en ålder av ≥ 60 år. Kvinnorna rekryterades från tre olika grupper; kvinnor som deltog i studie I, kvinnor som deltagit i en osteoporosskola mellan åren 2007 och 2010 samt kvinnor som svarade på en annons insatt i lokalpressen, vilket var majoriteten av de som deltog i studien. Inklusionskriterier för att delta i studien var diagnostiserad osteoporos och ryggvärk, 60 år eller äldre samt kunna delta i de interventioner som ingick i studien. De deltagande kvinnorna randomiserades till behandling med en aktiverande ryggortos, till en träningsgrupp med redskap på gym som leddes av fysioterapeut kombinerat med ett hemträningsprogram att utföra minst fyra gånger/vecka och till en kontrollgrupp. Studien pågick under en period av sex månader. Vid randomiseringsbesöket fick kvinnorna utföra en rad tester. Ryggmuskelstyrka, lungfunktion FVC, handgreppsstyrka, statisk och dynamisk balans, längd och vikt, ryggkurvatur mättes. De fick skatta sin ryggsmärta med VAS (Visuell Analog Skala) och med Borg CR-10 samt svara på flera frågeformulär; Riskfaktorer för osteoporos, livskvalitet och allmän hälsa (EQ-5D), och fallrisk med DFRI (Downton Fall Risk Index). Vid tre månader och vid studiens slut efter sex månader utfördes alla tester på nytt och alla frågeformulär besvarades igen.

Studie III var en kvalitativ studie där data analyserades med kvalitativ innehållsanalys. Insamling av data gjordes via fem fokusgruppsintervjuer, där 18 kvinnor från Studie II intervjuades om deras upplevelser och erfarenheter av att använda en aktiverande ryggortos.

Studie IV var en uppföljningsstudie sex månader efter avslutad intervention i Studie II (RCT) av de kvinnor som använt den aktiverande ryggortosen (n=38) och de kvinnor som tränat i träningsgruppen (n=38). I studien fick kvinnorna bära den aktiverande ryggortosen helt efter egna önskemål och de kvinnor som hade tränat i träningsgruppen fick träna helt självständigt under sex månader utan kontakt med primärvården. Frågeställningen i studien var om ryggsmärta, ryggstyrka och övriga variabler var förändrade efter ytterligare sex månader.

Resultat: Studie I: Röntgen av bröst- och ländrygg genomfördes på 74 kvinnor utav de 96 som deltog i studien. Det visades att 31% av kvinnorna hade en eller flera kotkompressioner. Jämförelse mellan kvinnor med hyperkyfos och kvinnor med normal kurvatur i bröstryggen visade att kvinnor med hyperkyfos (n=45) hade signifikant bättre förmåga till tandemstående med öppna ögon (18,3 sek jämfört med kvinnor utan hyperkyfos 12,7 sek), tandemgående framåt (5,2 steg jämfört med utan kyfos 3,6 steg) och tandemgående bakåt (6,9 steg jämfört med utan kyfos 4,1 steg). För kvinnor med hyperkyfos var åldersjusterad oddskvot (OR), med cut-off på 4 steg, att utföra tandemgående framåt 2,8 (CI 95% 1,1-7,4) och för tandem gående bakåt OR 4,5 (CI 95% 1,7-12,1,) jämfört med kvinnor utan hyperkyfos.

Studie II: En jämförande analys mellan de tre ingående grupperna i studien gjordes. Den visade ingen signifikant skillnad mellan de kvinnor som behandlats med den aktiverande ryggortosen i jämförelse med de kvinnor som tränat i träningsgruppen i kombination med ett hemträningsprogram och kontrollgruppen i ryggmuskelstyrka och ryggsmärta efter sex månaders intervention. I ryggortosgruppen hade de deltagande kvinnorna ökat sin ryggmuskelstyrka insignifikant med 27% (64,4 N till 81,7 N) (p=0,053) efter sex månader. Kvinnor som hade tränat enligt ett träningsprogram i gym i kombination med ett hemträningsprogram hade ökat sin ryggmuskelstyrka signifikant med 22% (59,6 N till 72,8 N) (p=0,013). Upplevd ryggsmärta graderad enligt VAS och Borg CR-10 visade ingen signifikant förändring i någon av grupperna vid studiens slut.

Studie III: Det övergripande temat som framkom var:” En väl anpassad ryggortos kunde utvecklas till en långvarig vänskap som gav stöd och underlättade dagligt liv”. Tre huvudkategorier framkom: Påverkan på dagligt liv, Individuell anpassning och Personlig relation.
Kvinnorna beskrev att den aktiverande ryggortosen kunde underlätta dagliga aktiviteter, att den kändes som ett stöd och minskade symtom från ryggen. De positiva effekterna var beroende av att ryggortosen var väl utprovad och anpassad till ryggen. Kvinnor beskrev att en relation till ryggortosen kunde utvecklas som kunde liknas vid en nära vänskap att stödja sig emot i det dagliga livet. men om den positiva upplevelsen inte infann sig utvecklades inte denna vänskap.

Studie IV: Analys gjordes mellan ortosgruppen, som fick använda ryggortosen helt efter egna önskemål och träningsgruppen, som tränade helt självständigt utan kontakt med primärvården under sex månader. Det fanns ingen skillnad mellan grupperna och ingen förändring av ryggmuskelstyrka, ryggsmärta eller övriga erhållna värden från RCT studien. vid sexmånaders post-intervention uppföljning.

Sammanfattning: Det övergripande syftet med denna avhandling var att öka kunskap om behandlingsmetoder och behandlingsalternativ som kan underlätta dagligt liv för äldre kvinnor med osteoporos och ryggvärk med eller utan kotkompression.

I denna avhandling rekryterades kvinnor ur två populationer dels äldre kvinnor med osteoporos och ryggvärk med eller utan kotkompression, och dels en kohort av äldre kvinnor som hade följts upp i tidigare studier under ca 15 år, födda mellan 1920 och 1930. Dessa kvinnor utgör en vanlig patientgrupp som söker primärvården.

Analys av röntgen bröst- och ländrygg bekräftade vad tidigare studier visat det vill säga att kotkompressioner är en diagnos som ofta inte upptäcks.

Behandling med en aktiverande ryggortos i jämförelse med träning i grupp i kombination med ett hemprogram samt med en kontrollgrupp visade ingen signifikant skillnad mellan grupperna i ryggsmärta och i ryggmuskelstyrka. Analys av förändring inom ortosgruppen och träningsgruppen visade att träningsgruppen ökade sin ryggmuskelstyrka signifikant, medan ökning av ryggmuskelstyrka hos ryggortosgruppen däremot inte var signifikant efter sex månaders intervention.

I den kvalitativa studien framkom ett övergripande tema. ”En väl anpassad ryggortos kunde utvecklas till en långvarig vänskap som utgjorde ett stöd och en hjälp i det dagliga livet”. I studien fick kvinnorna beskriva sina upplevelser av att använda ryggortosen. Det framkom att den aktiverande ryggortosen kunde underlätta dagliga aktiviteter som tidigare var svåra att utföra. Kvinnorna beskrev vidare att ryggen kändes starkare. Det var viktigt att ryggortosen var väl anpassad till ryggen och kändes bekväm för att den fortsättningsvis skulle bli använd.

Självständig användning av ryggortosen och självständig träning, utan kontakt med primärvården under sex månader, förändrade inte erhållna resultat av ryggmuskelstyrka, ryggsmärta eller övriga variabler från RCT studien.

Resultaten i denna avhandling indikerar att en aktiverande ryggortos skulle kunna användas som ett hjälpmedel och en träningsmetod för individer med osteoporos och ryggvärk som söker primärvården, men att fysisk aktivitet och träning som involverar och förbättrar flera kroppsliga funktioner bör väljas i första hand.

8 ACKNOWLEDGEMENTS

This thesis would never have been possible without the support and commitment I received from my outstanding supervisors, my colleagues, study assistants, friends and family. I would like to express my gratitude to:

Helena Salminen, my principal supervisor, who encouraged and believed in me. Enthusiasm, lots of support and great knowledge in the field of osteoporosis has come to me, which made the work with this thesis much easier.

Ann-Charlotte Grahn Kronhed, my co-supervisor, who contributed with fantastic support throughout the thesis. You have always shown great interest and contributed a lot of good advice based on deep knowledge.

Christina Olsson, my mentor who inspired me to choose the research path and over the years encouraged me to continue.

Agneta Aili Nolte, Elin Uzunel and Päivi Piispanen who in a committed and knowledgeable way examined and conduct surveys and questionnaires on the participants.

Lena Wahlberg who carefully handled all bookings and contacts with the participating women in the first study. She also collect all data of risk factors in the study.

Heidi Rocco and Eva Roxå, my former business managers, who showed great interest in my thesis and who made it possible to get time off for research and get access to premises for the examination of the participating women.

My colleagues at Rehab City, who have shown great interest and commitment in my work over the years and wanted to know more about the treatment of patients with osteoporosis and back pain at various training sessions and meetings.

Medi AB for contributing with the spinal orthosis which made it possible to conduct the RCT study in this thesis.

Ulf Odenblad and Embreis AB, with whom I have had a very pleasant collaboration over the years. Ulf has shown great interest in helping with education about the spinal orthosis as well as all contacts and questions that have arisen about the spinal orthosis during the thesis and also afterwards.

Kicki Drakander and Anette Dahl, orthopedic technicians, who carefully and with great knowledge tested and adapted the spinal orthosis to the women’s spinal curvature. The collaboration has been excellent.

Phd student group and research group, for inspiring discussions and interesting conversations.

All women who showed their interest in participating in the studies and who faithfully completed all tests, used the spinal orthosis and trained every week for six months.

Last but not least, my beloved husband who pushed me when it felt hard - it is invaluable!!

My beloved children Henric and Johanna with families who are a little impressed by their mother and mother-in-law!

My sister Suzanne who contributed with the cover image and thinks it is fantastic that it has become a thesis and my brother Anders who also thinks the same!

9 REFERENCES

1. Assessment of fracture risk and its application to screening for postmenopausal osteoporosis. Report of a WHO Study Group. World Health Organ Tech Rep Ser. 1994;843:1-129.

2. Hernlund E, Svedbom A, Ivergård M, et al. Osteoporosis in the European Union: medical management, epidemiology and economic burden. A report prepared in collaboration with the International Osteoporosis Foundation (IOF) and the European Federation of Pharmaceutical Industry Associations (EFPIA). Archives of Osteoporosis. 2013;8(1-2):136.

3. Miller PD. Guidelines for the diagnosis of osteoporosis: T-scores vs fractures. Rev Endocr Metab Disord. 2006;7(1-2):75-89.

4. Kanis JA, Johnell O, Oden A, et al. Long-term risk of osteoporotic fracture in Malmö. Osteoporosis International. 2000;11(8):669-674.

5. Bentler SE, Liu L, Obrizan M, et al. The aftermath of hip fracture: discharge placement, functional status change, and mortality. Am J Epidemiol. 2009;170(10):1290-1299.

6. Cauley JA, Hochberg MC, Lui LY, et al. Long-term risk of incident vertebral fractures. Jama. 2007;298(23):2761-2767.

7. Delmas PD, van de Langerijt L, Watts NB, et al. Underdiagnosis of vertebral fractures is a worldwide problem: the IMPACT study. J Bone Miner Res. 2005;20(4):557-563.

8. Hallberg I, Bachrach-Lindstrom M, Hammerby S, Toss G, Ek AC. Health-related quality of life after vertebral or hip fracture: a seven-year follow-up study. BMC Musculoskelet Disord. 2009;10:135.

9. Papaioannou A, Kennedy CC, Ioannidis G, et al. Determinants of health-related quality of life in women with vertebral fractures. Osteoporos Int. 2006;17(3):355-363.

10. Strom O, Borgstrom F, Zethraeus N, et al. Long-term cost and effect on quality of life of osteoporosis-related fractures in Sweden. Acta Orthop. 2008;79(2):269-280.

11. Genant HK, Wu CY, van Kuijk C, Nevitt MC. Vertebral fracture assessment using a semiquantitative technique. J Bone Miner Res. 1993;8(9):1137-1148.

12. Gehlbach S, Saag KG, Adachi JD, et al. Previous fractures at multiple sites increase the risk for subsequent fractures: the Global Longitudinal Study of Osteoporosis in Women. J Bone Miner Res. 2012;27(3):645-653.

13. Klotzbuecher CM, Ross PD, Landsman PB, Abbott TA, 3rd, Berger M. Patients with prior fractures have an increased risk of future fractures: a summary of the literature and statistical synthesis. J Bone Miner Res. 2000;15(4):721-739.

14. Ensrud KE, Black DM, Harris F, Ettinger B, Cummings SR. Correlates of kyphosis in older women. The Fracture Intervention Trial Research Group. J Am Geriatr Soc. 1997;45(6):682-687.

15. Kado DM, Lui LY, Ensrud KE, Fink HA, Karlamangla AS, Cummings SR. Hyperkyphosis predicts mortality independent of vertebral osteoporosis in older women. Ann Intern Med. 2009;150(10):681-687.

16. Katzman WB, Wanek L, Shepherd JA, Sellmeyer DE. Age-related hyperkyphosis: its causes, consequences, and management. J Orthop Sports Phys Ther. 2010;40(6):352-360.

17. Katzman WB, Vittinghoff E, Kado DM. Age-related hyperkyphosis, independent of spinal osteoporosis, is associated with impaired mobility in older community-dwelling women. Osteoporos Int. 2011;22(1):85-90.

18. Harrison RA, Siminoski K, Vethanayagam D, Majumdar SR. Osteoporosis-related kyphosis and impairments in pulmonary function: a systematic review. J Bone Miner Res. 2007;22(3):447-457.

19. Lombardi I, Jr., Oliveira LM, Mayer AF, Jardim JR, Natour J. Evaluation of pulmonary function and quality of life in women with osteoporosis. Osteoporosis International. 2005;16(10):1247-1253.

20. Culham EG, Jimenez HA, King CE. Thoracic kyphosis, rib mobility, and lung volumes in normal women and women with osteoporosis. Spine (Phila Pa 1976). 1994;19(11):1250-1255.

21. Sinaki M, Brey RH, Hughes CA, Larson DR, Kaufman KR. Balance disorder and increased risk of falls in osteoporosis and kyphosis: significance of kyphotic posture and muscle strength. Osteoporosis International. 2005;16(8):1004-1010.

22. Lynn SG, Sinaki M, Westerlind KC. Balance characteristics of persons with osteoporosis. Arch Phys Med Rehabil. 1997;78(3):273-277.

23. Brech GC, Fonseca AM, Bagnoli VR, Baracat EC, Greve JM. Anteroposterior displacement behavior of the center of pressure, without visual reference, in postmenopausal women with and without lumbar osteoporosis. Clinics (Sao Paulo). 2013;68(10):1293-1298.

24. Brech GC, Plapler PG, de Souza Meirelles E, Marcolino FM, Greve JM. Evaluation of the association between osteoporosis and postural balance in postmenopausal women. Gait Posture. 2013;38(2):321-325.

25. Eum R, Leveille SG, Kiely DK, Kiel DP, Samelson EJ, Bean JF. Is kyphosis related to mobility, balance, and disability? Am J Phys Med Rehabil. 2013;92(11):980-989.

26. Greig AM, Bennell KL, Briggs AM, Wark JD, Hodges PW. Balance impairment is related to vertebral fracture rather than thoracic kyphosis in individuals with osteoporosis. Osteoporos Int. 2007;18(4):543-551.

27. Ishikawa Y, Miyakoshi N, Kasukawa Y, Hongo M, Shimada Y. Spinal curvature and postural balance in patients with osteoporosis. Osteoporos Int. 2009;20(12):2049-2053.

28. Kasukawa Y, Miyakoshi N, Hongo M, et al. Relationships between falls, spinal curvature, spinal mobility and back extensor strength in elderly people. J Bone Miner Metab. 2010;28(1):82-87.

29. Grahn Kronhed A-C, Hallberg I, Ödkvist L, Möller M. Effect of training on health-related quality of life, pain and falls in osteoporotic women. Adv Physiotherapy. 2009;11(3):154-165.

30. Hongo M, Itoi E, Sinaki M, et al. Effect of low-intensity back exercise on quality of life and back extensor strength in patients with osteoporosis: a randomized controlled trial. Osteoporosis International. 2007;18(10):1389-1395.

31. Khalili A, Almasi MH, Raeissadat SA, Sedighipour L, Salek Zamani Y, Zohoor MRO. Long-term effects of back extensor strengthening exercises on quality of life in women with osteoporosis. Journal of women & aging. 2017;29(6):505-514.

32. Miyakoshi N, Hongo M, Maekawa S, Ishikawa Y, Shimada Y, Itoi E. Back extensor strength and lumbar spinal mobility are predictors of quality of life in patients with postmenopausal osteoporosis. Osteoporosis International. 2007;18(10):1397-1403.

33. Sinaki M, Itoi E, Wahner HW, et al. Stronger back muscles reduce the incidence of vertebral fractures: a prospective 10 year follow-up of postmenopausal women. Bone. 2002;30(6):836-841.

34. Sinaki M, Wollan PC, Scott RW, Gelczer RK. Can strong back extensors prevent vertebral fractures in women with osteoporosis? Mayo Clinic Proceedings. 1996;71(10):951-956.

35. Ball JM, Cagle P, Johnson BE, Lucasey C, Lukert BP. Spinal extension exercises prevent natural progression of kyphosis. Osteoporosis International. 2009;20(3):481-489.

36. Meccariello L, Muzii VF, Falzarano G, et al. Dynamic corset versus three-point brace in the treatment of osteoporotic compression fractures of the thoracic and lumbar spine: a prospective, comparative study. Aging clinical and experimental research. 2017;29(3):443-449.

37. Li M, Law S-w, Cheng J, Kee H-m, Wong MS. A comparison study on the efficacy of SpinoMed® and soft lumbar orthosis for osteoporotic vertebral fracture. Prosthetics and orthotics international. 2015;39(4):270-276.

38. Dionyssiotis Y, Trovas G, Thoma S, Lyritis G, Papaioannou N. Prospective study of spinal orthoses in women. Prosthetics and orthotics international. 2015;39(6):487-495.

39. Pfeifer M, Begerow B, Minne HW. Effects of a new spinal orthosis on posture, trunk strength, and quality of life in women with postmenopausal osteoporosis: a randomized trial. Am J Phys Med Rehabil. 2004;83(3):177-186.

40. Pfeifer M, Kohlwey L, Begerow B, Minne HW. Effects of two newly developed spinal orthoses on trunk muscle strength, posture, and quality-of-life in women with postmenopausal osteoporosis: a randomized trial. Am J Phys Med Rehabil. 2011;90(10):805-815.

41. Hübscher M, Schmidt K, Fink M, Vogt L, Banzer W. [Prospective evaluation of the effects of a spinal orthosis on physical function and quality of life in women with osteoporosis]. Z Orthop Unfall. 2010;148(4):443-447.

42. Schmidt K, Hübscher M, Vogt L, et al. [Influence of spinal orthosis on gait and physical functioning in women with postmenopausal osteoporosis]. Der Orthopäde. 2012;41(3):200-205.

43. Horak FB. Postural orientation and equilibrium: what do we need to know about neural control of balance to prevent falls? Age Ageing. 2006;35 Suppl 2:ii7-ii11.

44. Sinaki M, Brey RH, Hughes CA, Larson DR, Kaufman KR. Significant reduction in risk of falls and back pain in osteoporotic-kyphotic women through a Spinal Proprioceptive Extension Exercise Dynamic (SPEED) program. Mayo Clinic Proceedings. 2005;80(7):849-855.

45. Sherrington C, Fairhall NJ, Wallbank GK, et al. Exercise for preventing falls in older people living in the community. Cochrane library. 2019;1:CD012424.

46. Sherrington C, Fairhall N, Wallbank G, et al. Exercise for preventing falls in older people living in the community: an abridged Cochrane systematic Review. British journal of sports medicine. 2019.

47. Woollacott MH, Shumway-Cook A, Nashner LM. Aging and posture control: changes in sensory organization and muscular coordination. Int J Aging Hum Dev. 1986;23(2):97-114.

48. Sinaki M. Exercise for patients with osteoporosis: management of vertebral compression fractures and trunk strengthening for fall prevention. PM & R. 2012;4(11):882-888.

49. Burke TN, França FJ, Meneses SR, et al. Postural control among elderly women with and without osteoporosis: is there a difference? Sao Paulo Med J. 2010;128(4):219-224.

50. Lynn SG, Sinaki M, Westerlind KC. Balance characteristics of persons with osteoporosis. Arch Phys Med Rehabil. 1997;78(3):273-277.

51. Hsu WL, Chen CY, Tsauo JY, Yang RS. Balance control in elderly people with osteoporosis. J Formos Med Assoc. 2014;113(6):334-339.

52. Pfeifer M, Sinaki M, Geusens P, Boonen S, Preisinger E, Minne HW. Musculoskeletal rehabilitation in osteoporosis: a review. Journal of bone and mineral research. 2004;19(8):1208-1214.

53. Salminen H, Sääf M, Ringertz H, Strender LE. Bone mineral density measurement in the calcaneus with DXL: comparison with hip and spine measurements in a cross-sectional study of an elderly female population. Osteoporosis International. 2005;16(5):541-551.

54. Salminen H, Sääf M, Johansson SE, Ringertz H, Strender LE. Nutritional status, as determined by the Mini-Nutritional Assessment, and osteoporosis: a cross-sectional study of an elderly female population. Eur J Clin Nutr. 2006;60(4):486-493.

55. Salminen H, Sääf M, Ringertz H, Strender LE. The role of IGF-I and IGFBP-1 status and secondary hyperparathyroidism in relation to osteoporosis in elderly Swedish women. Osteoporosis International. 2008;19(2):201-209.

56. Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. Nurse Educ Today. 2004;24(2):105-112.

57. Elo S, Kyngäs H. The qualitative content analysis process. J. J Adv Nurs. 2008;62(1):107-115.

58. Price DD, McGrath PA, Rafii A, Buckingham B. The validation of visual analogue scales as ratio scale measures for chronic and experimental pain. Pain. 1983;17(1):45-56.

59. Hawker GA, Mian S, Kendzerska T, French M. Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant Osteoarthritis Pain (ICOAP). Arthritis care & research. 2011;63 Suppl 11:S240-S252.

60. Capodaglio EM. Comparison between the CR10 Borg's scale and the VAS (visual analogue scale) during an arm-cranking exercise. Journal of occupational rehabilitation. 2001;11(2):69-74.

61. Borg G. Principles in scaling pain and the Borg CR Scales®. Psychologica. 2004;37:35-47.

62. Moreau CE, Green BN, Johnson CD, Moreau SR. Isometric back extension endurance tests: a review of the literature. J Manipulative Physiol Ther. 2001;24(2):110-122.

63. Barrett E, McCreesh K, Lewis J. Intrarater and interrater reliability of the flexicurve index, flexicurve angle, and manual inclinometer for the measurement of thoracic kyphosis. Rehabilitation research and practice. 2013;2013:475870.

64. Lundon KM, Li AM, Bibershtein S. Interrater and intrarater reliability in the measurement of kyphosis in postmenopausal women with osteoporosis. Spine. 1998;23(18):1978-1985.

65. Luc Vereeck, Floris Wuyts, Steven Truijen, Heyning PVd. Clinical assessment of balance: normative data and gender and age effects. International Journal of Audiology. 2008;47(2),:67-75.

66. Franchignoni F, Tesio L, Martino MT, Ricupero C. Reliability of four simple, quantitative tests of balance and mobility in healthy elderly females. Aging (Milano). 1998;10(1):26-31.

67. Nyberg L, Gustafson Y. Using the Downton index to predict those prone to falls in stroke rehabilitation. Stroke. 1996;27(10):1821-1824.

68. Williams A. Euro-Qol - A new facility for the measurement of health-related-quality-of-life. Health policy. 1990;16(3):199-208.

69. Brooks R. EuroQol: the current state of play. Health policy. 1996;37(1):53-72.

70. Bergström I, Bergström K, Grahn Kronhed AC, Karlsson S, J. B. Back extensor training increases muscle strength in postmenopausal women with osteoporosis, kyphosis and vertebral fractures. Adv in Physiotherapy. 2011;3:110-117.

71. Giangregorio LM, Papaioannou A, Macintyre NJ, et al. Too Fit To Fracture: exercise recommendations for individuals with osteoporosis or osteoporotic vertebral fracture. Osteoporosis International. 2014;25(3):821-835.

72. Li WC, Chen YC, Yang RS, Tsauo JY. Effects of exercise programmes on quality of life in osteoporotic and osteopenic postmenopausal women: a systematic review and meta-analysis. Clin Rehabil. 2009;23(10):888-896.

73. Çergel Y, Topuz O, Alkan H, Sarsan A, Sabir Akkoyunlu N. The effects of short-term back extensor strength training in postmenopausal osteoporotic women with vertebral fractures: comparison of supervised and home exercise program. Archives of Osteoporosis. 2019;14(1):82.

74. Hedeker D, Gibbons RD. Longitudinal data analysis: Wiley-Interscience; 2006.

75. Elo S, Kääriäinen M, Kanste O, Pölkki T, Utriainen K, H K. Qualitative Content Analysis: A Focus on Trustworthiness,. SAGE Open. 2014;4:1-10.

76. Graneheim UH, Lindgren BM, Lundman B. Methodological challenges in qualitative content analysis: A discussion paper. Nurse Educ Today. 2017;56:29-34.

77. Elo S KM, Kanste O, Pölkki T, Utriainen K and Kyngäs H. Qualitative Content Analysis: A Focus on Trustworthiness,. Vol 4:. SAGE Open2014.

78. Elo S, Kääriäinen M, Kanste O, Pölkki T, Utriainen K, H K. Qualitative Content Analysis: A Focus on Trustworthiness,. SAGE Open. 2014;4::1-10.

79. Cohen J. Statistical power analysis for the behavioral sciences, 2nd edn. L. Erlbaum Associates, Hillsdale. Vol 2nd edn. Erlbaum Associates, Hillsdale1988.

80. Nuti R, Caffarelli C, Guglielmi G, Gennari L, Gonnelli S. Undiagnosed vertebral fractures influence quality of life in postmenopausal women with reduced ultrasound parameters. Clin Orthop Relat Res. 2014;472(7):2254-2261.

81. Pongchaiyakul C, Charoensri S, Leerapun T, Wongsiri S, Songpatanasilp T, Taechakraichana N. Prevalence of asymptomatic radiographic vertebral fracture in postmenopausal Thai women. Archives of Osteoporosis. 2020;15(1):78.

82. Li Y, Yan L, Cai S, Wang P, Zhuang H, Yu H. The prevalence and under-diagnosis of vertebral fractures on chest radiograph. BMC Musculoskelet Disord. 2018;19(1):235.

83. Saito T, Sterbenz JM, Malay S, Zhong L, MacEachern MP, Chung KC. Effectiveness of anti-osteoporotic drugs to prevent secondary fragility fractures: systematic review and meta-analysis. Osteoporosis International. 2017;28(12):3289-3300.

84. Sinaki M, Pfeifer M, Preisinger E, et al. The role of exercise in the treatment of osteoporosis. Current osteoporosis reports. 2010;8(3):138-144.

85. Ensrud KE, Black DM, Harris F, Ettinger B, Cummings SR. Correlates of kyphosis in older women. The Fracture Intervention Trial Research Group. J Am Geriatr Soc. 1997;45(6):682-687.

86. Kaijser Alin C, Grahn Kronhed A-C, Salminen H. The association between spinal curvature and balance in elderly women at highrisk of osteoporotic fractures in primary health care. European Journal of Physisotherapy. 2016;18:226-232.

87. Sinaki M, Brey RH, Hughes CA, Larson DR, Kaufman KR. Balance disorder and increased risk of falls in osteoporosis and kyphosis: significance of kyphotic posture and muscle strength. Osteoporos Int. 2005;16(8):1004-1010.

88. Pfeifer M, Begerow B, Minne HW. Effects of a new spinal orthosis on posture, trunk strength, and quality of life in women with postmenopausal osteoporosis: a randomized trial. American journal of physical medicine & rehabilitation. 2004;83(3):177-186.

89. de Groot MH, van der Jagt-Willems HC, van Campen JP, Lems WF, Lamoth CJ. Testing postural control among various osteoporotic patient groups: a literature review. Geriatr Gerontol Int. 2012;12(4):573-585.

90. Eum R, Leveille SG, Kiely DK, Kiel DP, Samelson EJ, Bean JF. Is kyphosis related to mobility, balance, and disability? Am J Phys Med Rehabil. 2013;92(11):980-989.

91. Ishikawa Y, Miyakoshi N, Kasukawa Y, Hongo M, Shimada Y. Spinal curvature and postural balance in patients with osteoporosis. Osteoporosis International. 2009;20(12):2049-2053.

92. Amiridis IG, Hatzitaki V, Arabatzi F. Age-induced modifications of static postural control in humans. Neurosci Lett. 2003;350(3):137-140.

93. Grahn Kronhed A-C, Hallberg I, Ödkvist L, Möller M. Effect of training on health-related quality of life, pain and falls in osteoporotic women. Vol 11(3). Adv Physiother2009.

94. Kaijser Alin C, Uzunel E, Grahn Kronhed AC, Alinaghizadeh H, Salminen H. Effect of treatment on back pain and back extensor strength with a spinal orthosis in older women with osteoporosis: a randomized controlled trial. Archives of Osteoporosis. 2019;14(1):5.

95. Sinaki M, Brey RH, Hughes CA, Larson DR, Kaufman KR. Balance disorder and increased risk of falls in osteoporosis and kyphosis: significance of kyphotic posture and muscle strength. Osteoporos Int. 2005;16(8):1004-1010.

96. Pfeifer M, Gehlen M, Hinz C. Spinal orthoses in the treatment of vertebral fractures with osteoporosis : A systematic review article. Zeitschrift für Rheumatologie. 2017;76(10):860-868.

97. Newman M, Minns Lowe C, Barker K. Spinal Orthoses for Vertebral Osteoporosis and Osteoporotic Vertebral Fracture: A Systematic Review. Archives of physical medicine and rehabilitation. 2016;97(6):1013-1025.

98. Jin YZ, Lee JH. Effect of Brace to Osteoporotic Vertebral Fracture: a Meta-Analysis. Journal of Korean medical science. 2016;31(10):1641-1649.

99. Kaijser Alin C, Frisendahl N, Grahn Kronhed A-C, Salminen H. Experience of using an activating spinal orthosis in women with osteoporosis and back pain. Archives of Osteoporosis. 2020;Accepted for publication may 2020.