

Hakestad, K. A., Torstveit, M. K., Nordsletten, L., Axelsson, Å. C., Risberg, M. A. (2015). Exercises including weight vests and a patient education program for women with osteopenia: a feasibility study of the OsteoACTIVE rehabilitation program. *Journal of Orthopaedic and Sports Physical Therapy*, *45*, 97-105.

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Exercises including weight vests and a patient education program for women with osteopenia. A feasibility study of the OsteoACTIVE rehabilitation program

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The study was supported with research grant from South-Eastern Norway Regional Health Authority.

Ethical approvement (Institutional Review Board): reference number 1.2005.82

www.clinicaltrials.gov reference number NCT01357278

#### ABSTRACT

Study Design: Prospective cohort study with 1-year follow-up.

**Objectives:** The primary aims were to describe the OsteoACTIVE rehabilitation program and evaluate its feasibility in terms of progression, adherence, and adverse events in patients with low bone mineral density (BMD) and with a healed forearm fracture. The secondary aims were to assess changes in measures of function and quality of life (QOL).

**Background:** Previous studies have shown benefits of weight-bearing activities, resistance exercises, and balance and coordination training for women with low bone mineral density (BMD) and older adults. However, no studies to our knowledge have described or examined a rehabilitation program combining the use of weight vests and patient education in patients with low BMD.

**Methods:** Forty-two postmenopausal women with osteopenia and a healed forearm fracture attended the OsteoACTIVE program for 6 months (3 sessions of 60 minutes per week). Feasibility was assessed by documenting training progression (load and exercises), program adherence (aiming for >80%), and adverse events (joint pain, muscle soreness, and falls). Secondary measures included quadriceps strength, BMD, dynamic balance, walking ability, and self-report functional outcome measures. All outcome measures were recorded pre- and post-intervention, and at 1-year follow-up.

**Results:** Thirty-five women (83%) completed the 6-month program and 31 women (74%) attended all the follow-up measurement sessions. All participants progressed during the rehabilitation program for both load and type of exercises. Furthermore, 87% of participants met the apriori 80% goal for adherence, and no participants reported adverse events. Improvement in quadriceps strength and BMD of the femur trochanter were noted at the end

of the 6 months training period (P<.05). At 1-year follow-up, there was significant improvements in quadriceps strength and dynamic balance compared to baseline (P<.05).

**Conclusion:** The OsteoACTIVE rehabilitation program was feasible and achieved progression of training level, had high adherence, and had no adverse events. Positive improvements were established in lower extremity function and femur trochanter BMD.

Key words: adverse events, bone mineral density, exercise, osteoporosis, osteopenia

### **INTRODUCTION**

Previous studies have reported decreased muscle strength and impaired balance as significant risk factors for falling in postmenopausal women with low bone mineral density (BMD) (osteopenia or osteoporosis). <sup>1, 7, 13, 35, 50</sup> These findings suggest that therapeutic exercise programs for individuals with low BMD should address these impairments by including weight-bearing exercises that incorporate balance and strength training. <sup>7, 15</sup> Furthermore, structured exercise therapy programs in postmenopausal women with low BMD has shown to improve quality of life (QOL). <sup>37</sup>

Progressive, high-intensity, resistance exercises has been demonstrated to improve muscle strength and physical function in older adults. <sup>38, 49</sup> Based on a systematic review of exercise in patients with low BMD, Vuori et al<sup>57</sup> suggested that progressive resistance training with high-intensity loading was more effective than low-intensity loading to improve BMD. However, the dose-response relationship between loading and improvements in BMD is unknown.<sup>57</sup> Progressive resistance training has been reported to be safe for older adults.<sup>20, 54</sup> But, the use of weight vests during exercise in individuals with low BMD without a history of previous fractures, has to our knowledge only been reported in 2 studies. <sup>55, 56</sup> These studies reported significant improvements in muscle strength and dynamic balance, but no change in BMD. <sup>55, 56</sup> Other studies using weight vests in older adults with normal BMD values have shown conflicting results in their effectiveness in improving muscle strength, balance, and BMD. <sup>4, 25, 26, 33</sup> Weight vests can be used to increase the forces placed on the spine and the lower extremities with the goal to increase load to the skeletal system and to improve muscle strength. <sup>51</sup> Therefore, weight vests could be used to increase exercise intensity, progression of strength training, and increase load on the musculoskeletal system in older adults with low BMD.

Most previous studies examining the effect of exercise therapy in older adults have included women with either normal or low BMD, but without a history of fracture. <sup>15, 21</sup> Very few studies have included women with low BMD and a history of fracture. <sup>5, 11, 43</sup>

As interventions should focus on prevention aspects for patients who are at risk of developing osteoporosis, a feasibility study describing the content of such a rehabilitation program is needed. To our knowledge, only 1 exercise program for postmenopausal women with osteopenia has previously been described in the literature, <sup>6</sup> but with little attention to document the feasibility of the program.

The primary aims of this study were therefore to describe the exercises and the patient education included in the OsteoACTIVE rehabilitation program and to document the feasibility and adherence to the program along with any potential adverse events. The secondary aims were to examine changes in lower extremity function and QOL at the end of the 6 month intervention and at 1-year follow-up.

#### **METHODS**

Participants included in this prospective cohort study with 1-year follow-up were recruited from the Department of Orthopaedic Surgery and the Emergency Ward at the Oslo University Hospital in Norway. These participants are also part of an on-going randomized controlled trial (www.clinicaltrials.gov; reference number NCT01357278).

The inclusion criteria for the study were: (1) low BMD (t-score < - 1.5); <sup>34</sup> (2) postmenopausal women older than 50 years of age; <sup>24</sup> (3) wrist fracture that occurred no longer than 2 years ago and was healed at the time of inclusion; and (4) residing in the Oslo region. The exclusion criteria were: (1) a history of hip or vertebral fracture; (2) a history of more than 3 osteoporotic fractures; (3) medical problems/illnesses precluding active rehabilitation; (4) already performing moderate to intense physical activity for more than 4 hours per week; and (5) inability to understand written or spoken Norwegian.

Ethical approval for the study protocol was obtained from the Regional Committee for Medical Research Ethics for South-Eastern Norway. All participants received verbal and written information about the study and signed an informed consent. The data collection was conducted in accordance with the Declaration of Helsinki.

### Intervention

The active rehabilitation program, OsteoACTIVE, consisted of a 6-month exercise program combined with a patient education program called OsteoINFO. The exercise program consisted of 2 group exercise and 1 home exercise session per week for a total of 3 sixty-

minute sessions per week. The OsteoINFO education program was given twice during the 6month intervention period.

The group-sessions included 10 minutes of warm-up (walking and stretching), the primary component for 40 minutes, and 5 to 10 minutes of cool-down (walking and stretching). The included exercises with progression and duration information are described in detail in the **APPENDIX**. The exercises were conducted in a group to enhancing group dynamics and emotional well-being. <sup>3</sup> It was also intended to increase motivation for engaging in physical activity as well as to reduce the tension and anxiety related to fear of falling and fear of fractures.

The exercise program focused on progression in intensity and types of exercises, and was based on an established Danish model <sup>43</sup> and the Osteofit, a model developed at the University of British Columbia, Canada. <sup>10, 11</sup> A certified orthopaedic physical therapist was designated as the instructor of the group sessions. The program included exercises for strength, balance, coordination, and core stability and included the use of weight vests. Ergonomic exercises, such as rising up from lying to a standing position and lifting heavy items (5 kg dumb bells) while maintaining the spine in a neutral position and keep the items close to the body, were also incorporated in the program. The exercises were standardized and performed as 2 to 3 sets of 5 to 12 repetitions based on the recommendations for progression for strength training for healthy adults. <sup>36, 48</sup> The rate of progression was based on recommendations for improving muscle strength in the elderly, but was also tailored to the group, as well as each individual's response, level of functioning, and co-morbidities (eg, irregular heartbeat, hypertension, and chronic obstructive lung disease). Group sizes of 6 to 10 participants allowed the program to

be tailored to specific individuals. Briefly, strengthening exercises for the lower limbs consisted of squats and lunges to strengthen lower limb muscles while shoulder and arm strengthening exercises (biceps-, triceps-, and side curls) were also performed. Core strengthening exercises consisted of crunches, side-lying planks, bridging, and backlifts while the balance component of the program consisted of semi-tandem and single leg static and dynamic exercises. The group-based program was performed with background music adjusted for the age group with rhythmic components for pacing the intensity and the characteristics of the exercises. <sup>45</sup>

The home session was performed with the help of an exercise dvd published by the Norwegian Association for Osteoporosis. The session included 10 minutes of warm-up, 40 minutes with exercises for strength, balance, and core stability, and 10 minutes of stretching.

### Patient education; OsteoINFO

The OsteoINFO component was provided as a group-based patient education program led by an athletic trainer with a PhD on the topic of osteoporosis (M.K.T.) and consisted of 2 sessions. The first session was provided after 8 weeks and the second session after 16 weeks. Each session was 2 hours in duration and included lectures and discussions. OsteoINFO was based on the program entitled "Choices for Better Bone Health", <sup>23</sup> and the primary aims were similar to those described by Gold and McClung. <sup>22</sup>

# Feasibility

Feasibility of the exercise program was examined by recording progression of training (load and exercises), adherence, and adverse events.

The progression of the program was divided into 2 levels. Level 1 was followed for the first 3 months after an initial familiarization period of 2 weeks where the technique for the different exercises was practiced with 2 sets of 5 to 12 repetitions. Following the familiarization period, the participants gradually increased the volume and intensity of each exercise using 3 sets of 10 to 12 repetitions. During the last 3 months of the program, Level II was introduced with higher intensity, increased load (with weight vest), and increased exercise complexity. Progression of loads was ensured with weight vests and more challenging stability and coordination exercises, and with 3 sets of 8 to 10 repetitions. Each weight vest was able to hold 9 weights, each 1.1kg.

Adherence to the rehabilitation program was registered by the group instructor. The 24-week intervention, with 2 weekly group exercise sessions, consisted of a maximum of 48 group exercise sessions. We selected a threshold of 80% attendance for acceptable adherence, which represented 38 group exercise sessions. The participants were told to record all daily physical activity in a personal training diary. The aim of using training diaries was to obtain information about frequency, duration, and type of physical activity performed during their leisure time (including the home exercise program).

The participants were asked to report to the supervising physical therapist after each training session if any adverse events such as joint pain, muscle soreness, and fall events related to the exercises occurred during the session, or had occurred at any other time during their leisure time activities. Fall events were monitored during the exercise sessions, while muscle soreness and joint pain were recorded by the patients also between the exercise sessions. Adverse events were noted in the training diary and medical records.

### **Secondary Measures**

All outcomes measures were obtained by an independent investigator at prior and after the 6 month program and also at 1 year follow-up.

*Strength* Quadriceps strength was assessed using a Biodex 6000 isokinetic dynamometer (Biodex 3 System Pro, USA) and values were expressed as peak torque in Newton meters (Nm) and total work in Joules (J) for testing at 60° and 180° per second. Strength assessment is highly reliable (ICC=0.89-0.93) for postmenopausal women with osteopenia. <sup>18</sup>

*Anthropometry* Height, weight, absolute and percentage fat, and fat-free mass were measured by means of weight and height scales and dual-energy x-ray absorptiometry (DXA, GE Lunar scan Prodigy, enCORE version 11.2). BMD was measured by means of DXA. Changes in BMD of at least  $\pm 0.04$  g/cm<sup>2</sup> at the lumbar spine and  $\pm 0.02$  g/cm<sup>2</sup> at the hip have shown to represent a minimal detectable change. <sup>39</sup> The scanned areas were hip, femoral neck and trochanter, lumbar spine, and total body.

*Balance* Dynamic standing balance was evaluated with the Four Square Step Test (FSST). <sup>17</sup> The FSST has been tested for reliability (ICC=0.99) and validity with a sensitivity of 85% and a specificity of 88% to 100%. <sup>17</sup>

*Walking* Walking capacity was evaluated using the 6-minute walk test (6MWT); <sup>2, 9, 19</sup> which has been validated for measuring functional capacity in elderly people. <sup>19</sup> An improvement of 54 meters is considered clinically relevant. <sup>60</sup> Following the 6MWT, the level of perceived exertion was recorded using the Borg scale from 6 to 20, where 6 indicates "very easy" and

20 indicates "very exhausting". <sup>8, 12</sup> An improvement of 2 units is considered to be an important change. <sup>52</sup>

*Function* Physical activity level was evaluated using the validated self-reported physical activity scale for the elderly (PASE). <sup>16, 59</sup> We used the modified Norwegian version on a scale from 0 to 315, where higher scores reflect a higher activity level.<sup>41</sup>

*Quality of life* Health-related quality of life (QOL) was evaluated using the Short Form 36 (SF-36). <sup>58</sup> The instrument is divided into 8 sub-scales, each on a scale from 0 to 100, and includes aspects of physical function, role limitations-physical, bodily pain, general health, vitality, social function, role limitations-emotional, and mental health. The SF-36 has demonstrated high levels of reliability and validity, <sup>44</sup> and an improvement of 3 to 5 points has been considered clinically relevant. <sup>28, 53</sup>

# **Data Analysis**

Analyses were performed using Statistical Package for Social Sciences 19.0 (SPSS) for Windows (SPSS Inc., Chicago, Illinois). Descriptive data for the primary variables adherence and adverse events were calculated from frequencies, mean values and range. Data on the variables; strength, anthropometry, balance, walking, function and quality of life were used by a 1-way within-subjects analysis of variance (ANOVA) at pre-intervention (time 1), postintervention (time 2) and 1-year (after pre-intervention) (time 3). <sup>47</sup> The level of statistical significance was set to 0.05.

# RESULTS

Of the 42 participants who were included in the 6-month OsteoACTIVE program, 3 withdrew prior to the testing after the intervention. Total hip replacement, severe knee osteoarthritis, and personal reasons prevented 3 other participants from completing the intervention. Furthermore, 1 participant was lost to follow-up, leaving 35 who completed the 6-month program (83%). At 1-year follow-up, 4 other participants were lost to follow-up (74%). We therefore have complete data (pre- and post-intervention and 1-year follow-up) on 31 participants (74%) (TABLE 1).

All participants started the intervention using two 1.1 kg weights in the vest, which was later increased to 4 and 6 weights for progression. By the end of the program (end of level II), all participants except 3 were able to perform weight-bearing exercises with all 9 weights in the vest. The remaining 3 individuals used 7 weights.

The mean adherence rate for the 48 exercise sessions during the 6-months of the study for the 35 participants who completed the intervention was 87% (range 48-100%). Because many participants did not complete the leisure time training diaries, these could not be used to calculate the physical activity level outside of the group-based training sessions.

No adverse events were recorded, but 3 participants (1 each with an old neck injury, severe hip osteoarthritis, and Sjogren's Syndrome) had to limit the use of weights in the vest to 7 for their weight-bearing exercises.

From pre- to post intervention, there was a statistically significant increase in quadriceps strength for the left knee based on peak torque at  $60^{\circ}$ /s (P=.04; **TABLE 2**). Total work ( $60^{\circ}$ /s) increased significantly for both limbs: 7% increase for the left limb, P=.01, and 8% increase for the right limb, (P=.007; **TABLE 2**). For total work at 180°/s, there was a significant increase of 8% (P=.001) for the left limb, and a significant increase of 10% (P<.001) for the right limb (**TABLE 2**). At the 1-year follow-up, quadriceps strength (peak torque at  $60^{\circ}$ /s) for the left limb was11% greater than at pre-intervention (P=.002; **TABLE 2**). Total work ( $60^{\circ}$ /s) was also significantly greater: 15% greater (P<.001) for the left limb and 11% greater for the right limb (P=.001; **TABLE 2**). Total work at 180°/s was also significantly greater: 7% for both left (P=.002) and right (P=.03) limb (**TABLE 2**).

BMD in the femur trochanter increased by 2.4% from pre- to post-intervention \_(P=.011; **TABLE 3**). There was a significant increase of 0.6% in BMD for the total hip from pre- to post-intervention (P=.005; **TABLE 3**). No significant differences were noted between from pre-intervention and the 1-year follow-up for the BMD values (**TABLE 3**).

There was also a significant mean improvement of 1.6 seconds on the test of dynamic balance (P=0.03) at the 1-year follow-up (**TABLE 4**). But there were no statistically significant changes for walking capacity, physical activity level (**TABLE 4**), and quality of life (**TABLE 5**) at either post-intervention or at the 1-year follow-up.

#### DISCUSSION

The progression in training level, the high adherence level, and the absence of adverse events provides support for the feasibility of the OsteoACTIVE program for women with osteopenia. The results from the 6-month active rehabilitation program also suggest the potential for positive changes in quadriceps strength and BMD in femur trochanter by the end of the intervention. Finally, positive changes in quadriceps strength and dynamic balance were also noted at 1 year when compared to pre-intervention values. To our knowledge, this is the first study describing a rehabilitation program in detail, evaluating its feasibility, and assessing changes in lower extremity function and QOL in postmenopausal women with osteopenia *and* a recent healed forearm fracture.

Our results showed that sufficient progression to increase muscle strength occurred within the active rehabilitation program. This was achieved by dividing the active rehabilitation program into 2 levels starting with 2 to 3 sets of 5 to12 repetitions and progressed with 3 sets of 8 to 10 repetitions with higher intensity, increased load by using weight vests, and increased difficulty of exercises. All participants were able to follow this progression, however, not all were able to progress to the highest loading of 9 weights in the vests. The only previously published rehabilitation program for women with osteopenia, resulted in no significant improvements in quadriceps strength, probably, due to lack of progression and loading during the exercises.  $^{6}$ 

The mean adherence to the OsteACTIVE rehabilitation program was 87 %, with 74% of participants attending more than 80% of the exercise sessions. Our high adherence rate was similar to other studies with duration of 6 months. <sup>30</sup> The high adherence rate might be due to our OsteoACTIVE program including both a group-based aerobic exercise-program in addition to the group-based patient education program. Another important factor related to the

adherence rate could be the duration of our exercise program. Adherence to the exercise program was registered by the instructor of the group sessions.

The participants were also supposed to record their physical activities during leisure time and home program in their training diaries. However, they did not comply effectively with the use of their training diaries, and we were not able to report information about their physical activities during their leisure time. In the future, similar studies should include web-based questionnaires regarding the daily activities between the sessions and/or having a person to call the participants weekly to answer a questionnaire regarding predefined activities.

In the recent Cochrane review by Howe et al,<sup>30</sup> falls were reported as adverse events in 3 similar studies, and muscle soreness, joint pain, headache, and itching were reported as adverse events in 11 studies among postmenopausal women with low BMD. In contrast to these findings, we found no adverse events during our 6-month exercise program. It should be noted, however, that the supervising physiotherapist only encouraged the participants to state after the group sessions if any adverse events related to the exercises had occurred. To further improve the monitoring of possible adverse events we should also have asked each participant to complete a questionnaire regarding predefined adverse events and/or interviewed each participant asking the same questions (instead of asking a generic question after each group session). Furthermore, the physiotherapist should have monitored adverse events more closely (weekly using electronic reminders) related to falls or other events during daily life (outside of the training sessions).

Pfeifer et al<sup>50</sup> highlighted the role of muscle strengthening in preventing osteoporotic fractures and falls for patients with low BMD, including those with a recent healed forearm fracture. Studies have shown that strengthening exercises for the lower extremity muscles have a positive effect on reducing the risk of fractures. <sup>50</sup> However, there is no clear

consensus on the selection of appropriate exercises and dosage in patients with low BMD. We implemented standardised muscle strength, balance, coordination, and core stability training and included the use of weight vests with a frequency and intensity consistent with previous descriptions of exercises to promote muscle hypertrophy and balance in elderly individuals.<sup>1,</sup> <sup>32, 38</sup> Post-intervention, a significant improvement in quadriceps strength (peak torque at  $60^{\circ}/s$ ) was found for the left limb, and in total work at both  $60^{\circ}$ /s and  $180^{\circ}$ /s for both limbs. Our findings are consistent with those of a systematic review of deKam et al, <sup>15</sup> who found 3% to 28% improvement in quadriceps strength in people with low BMD following an exercise program with a duration from 12 to 30 weeks. This study demonstrated that a training frequency of more than 2 times a week has a positive effect on muscle strength. <sup>15</sup> Our data suggest that individuals with osteopenia and a recent healed forearm fracture have potential for lower extremity functional improvements after the OsteoACTIVE rehabilitation program consisting of 2 weekly group exercise sessions and a patient education program. Participants also maintained their quadriceps strength after the end of the program to the 1-year follow-up, in particular for total work measured at  $60^{\circ}$ /s with 15% for the left limb indicating a clinical improvement. This is in line with the study by Eitzen et al. <sup>18</sup> suggesting clinically important differences between 15% and 20% for knee extension.

BMD in femur trochanter increased significantly with 2.4% from pre- to posttest. In the meta-analysis by Howe et al. <sup>30</sup> they found an improvement of 1% when progressive resistance strength training was used. Of the 43 RCTs, eight of the studies involved an exercise program of three times a week lasting for six months. In contrast to our findings, none of these studies found any significant improvements in BMD. In the review by Guadalupe-Grau et al., <sup>27</sup> a period of 12-18 months of weight training is recommended to gain BMD for postmenopausal women. Furthermore, none of the hip or spine values in our study exceeded the limits of clinically important changes. <sup>39</sup> A Cochrane review, <sup>31</sup> concluded that exercises involving gait, balance, coordination (hand-eye and foot-eye, dynamic, standing and leaning balance, and reaction time combined with high intensity resistance training), functional exercises, and muscle strengthening improve balance among older adults. Coordination training has shown to be important for preventing falls among elderly people, <sup>21, 35</sup> where dizziness and unsteadiness might be brought on by age-related changes in the brain. <sup>29, 46</sup> Improvements in quadriceps strength may also explain the significant improvements in dynamic balance in our participants. Previous studies have found a significant association between reduced quadriceps strength and poor balance, resulting in an increased sway and risk of falling. <sup>29, 42</sup> This is especially important in the elderly population because increasing age results in loss of type 2 muscle fibres, leading to slower reaction time and reduced ability to correct postural imbalance, adding to fall risks. Based on our findings, it seems possible to achieve significant improvements in both muscle strength and dynamic balance with a 6 month active rehabilitation program that uses a gradual progression in type of exercises and loading with the use of weight vests.

The rehabilitation program did not result in increased walking capacity as measured with the 6MWT. Furthermore, to achieve a clinically important change, an improvement of 54 metres had to be exceeded. <sup>60</sup> This may have been due to a ceiling effect, as walking capacity was already similar to that of healthy elderly prior to the intervention. <sup>2</sup>

The mean score for all subscales of the SF-36 was higher at pre-intervention in our participants than what is typically found among age-matched populations. <sup>40</sup> No significant improvements were found for any of the subscales of the SF-36 as a result of the intervention. To our knowledge, the SF-36 subscales have not previously been used to monitor outcome for older individuals with low BMD. It is possible that a disease-specific questionnaire may be more sensitive to changes resulting from an intervention as used in this study. <sup>37</sup> Additional

research is required to define clinically important changes for the SF-36 subscales for individuals with low BMD.<sup>14</sup>

Patient education has been considered an important component for compliance to many different treatment programs across a broad range of conditions. <sup>22</sup> However, it remains uncertain as to whether or not patient education programs improve compliance to exercise interventions for patients with low BMD. Nevertheless, all participants in our study gave positive feedback about the patient education program, indicating that this component of the program was likely to be an important part of the intervention. This is in agreement with the conclusions presented by Gold and McClung. <sup>22</sup>

Based on the significant improvements we found in quadriceps strength and dynamic balance, our rehabilitation program could be used in future studies. But furthermore, our data on changes in quadriceps strength and balance could be used to calculate statistical power for future clinical trials, and for including variables related to risk of falls for this population, and of course for further development of evidence-based rehabilitation programs for individuals with low BMD.

# Limitations

Due to the small sample size, and the lack of a control group, data on the efficacy of the program need to be considered with caution. This is consistent with the study's primary purpose of examining feasibility of the intervention. The most important weakness of a single-group study, is the threat to internal validity such as learning and time effects. Furthermore, our study was not designed to determine if this rehabilitation program in women with osteopenia would reduce the development of osteoporosis or risk factors for falls.

Future rehabilitation studies should include a better method to monitor falls and other adverse events, potentially using web-based questionnaires or other approaches to regularly monitor

adverse events during and after the supervised training sessions as well as daily activities between the sessions. Furthermore, the assessment of patients' perception of changes with a self-report questionnaire could have provided valuable information. Another limitation was that the participants did not complete their home training diaries. Thus, we were unable to report information about the physical activities during leisure time, a variable that could have affected the outcome measures we examined.

#### **CONCLUSION**

A 6-month active rehabilitation program including an exercise program with the use of weight vest in addition to a patient education program was feasible and showed progression of type of exercises and loading, as well as high adherence, and with no self-reported adverse events during training sessions among postmenopausal women with osteopenia.

# **KEY POINTS**

# FINDINGS

A 6-month active rehabilitation program including an exercise program with the use of weight vest in addition to a patient education program was feasible, had sufficient progression, and had high adherence with no adverse events. Furthermore, the exercise program led to significant improvements in lower extremity function and femur trochanter BMD.

# **IMPLICATIONS**

The active rehabilitation program could be implemented in future studies in women with low BMD and a healed forearm fracture to improve muscle strength, balance and BMD, some of the most important risk factors for fall and fracture.

#### CAUTION

The results cannot be generalized to patients with severe established osteoporosis, nor those with vertebral or hip fracture, and the effectiveness of the program needs to be studied in a randomized controlled trial.

# ACKNOWLEDGMENTS

The study was supported with research grant from South-Eastern Norway Regional Health Authority. We acknowledge the Norwegian Sport Medicine Clinic, Oslo, Norway for supporting the Norwegian Research Center for Active Rehabilitation (<u>www.active-rehab.no</u>) with rehabilitation facilities and research staff. The Norwegian Research Center for Active Rehabilitation is a collaboration between the Norwegian School of Sport Sciences, Department of Orthopaedic Surgery, Oslo University Hospital and the Norwegian Sport Medicine Clinic. We also like to acknowledge Kristin Bølstad, Marte Lund and Annika Storevold as instructors for the exercise group.

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Characteristics	Values		
Age (years)	65.5	<b>±</b> 7.1	
Height (cm)	164.2	<b>±</b> 6.9	
Weight (kg)	65.9	<b>±</b> 11.2	
BMI (kg/m <sup>2</sup> )	24.6	<b>±</b> 4.3	
Age of menarche (years)	13.4	<b>±</b> 1.7	
Age of menopause (years)	48.9	<b>±</b> 5.4	
Years post menopause	17.2	<b>±</b> 9.2	
Current use of bisphosphonate, n (%)	6	(19.4)	
Current use of calcium, n (%)	1	(3.2)	
Years since fracture by inclusion	1.7	<b>±</b> 0.9	
Past history of fracture, median (min-max)	2	(1-3)	
Family history of osteoporosis n (%)	9	(47)	
Current smoker n (%)	4	(12.9)	
Previous smoker n (%)	8	(25.8)	
Current alcohol use, 4-7 units/week n (%)	3	(16)	
Educational attainment: higher degree > 3 (years), n (%)	14	(45.2)	
lower degree < 3 (years), n (%)	17	(54.8)	

# **TABLE 1:** Participant characteristics (n=31)

Mean and SD, unless otherwise indicated BMI=body mass index

**TABLE 2:** Quadriceps strength from pre- to post-intervention, and from pre-intervention to 1-year follow-up (n=31) 1

				Change from pre- to post-	Change from pre-intervention
				intervention	to 1 year
	<b>Pre-intervention</b>	<b>Post-intervention</b>	1 year	Mean (95% CI)	Mean (95% CI)
Right peak torque 60°/sec (Nm)	97.1 ± 25.7	$101.9\pm23.8$	$104.4 \pm 22.7$	4.8 (-2.9 to 12.6)	7.3 (-0.04 to 14.6)
Left peak torque 60°/sec (Nm)*	89.2 ± 24.3	$97.0\pm22.5$	$99.7\pm25.9$	7.8 (0.3 to 15.3) <sup><math>\dagger</math></sup>	10.5 (3.5 to 17.5) <sup>‡</sup>
Right total work 60°/sec (J)	$426.5\pm123.1$	$464.9\pm109.9$	$479.0 \pm 113.0$	38.4 (9.1 to 67.7) <sup>‡</sup>	52.5 (21.0 to 83.9) <sup>§</sup>
Left total work $60^{\circ}/\text{sec}(J)^*$	$386.4 \pm 117.0$	$430.2\pm112.6$	$452.0\pm118.0$	43.8 (8.7 to 78.8) <sup>†</sup>	65.6 (35.1 to 96.1) <sup>§</sup>
Right total work 180°/sec (J)	$1228.9\pm313.3$	$1371.9\pm317.4$	$1323.7 \pm 339.5$	143 (72.3 to 213.6) <sup>§</sup>	94.8 (5.9 to 183.5) <sup>†</sup>
Left total work $180^{\circ}/\text{sec}(J)^*$	1122.8 ± 306.9	$1252.7 \pm 321.7$	$1236.5 \pm 341.7$	129.9 (52.7 to 206.9) <sup>§</sup>	113.7 (39.2 to 192.4) <sup>‡</sup>

 $Nm=Newton\ meter,\ J=Joule^*n=30\ at\ posttest,\ 1\ participant\ was\ not\ tested\ due\ to\ fracture\ in\ left\ ankle$ 2 3

 $^{\dagger}p$ -value <0.05

 $\hat{t}$ *p-value* <0.01

4 5  $\hat{s}$ p-value<0.001

				Change from pre- intervention to post- intervention	Change from pre- intervention to 1 year
	<b>Pre-intervention</b>	<b>Post-intervention</b>	1 year	Mean (95% CI)	Mean (95% CI)
BMI (kg/m <sup>2</sup> )	$24.6\pm4.3$	$24.6\pm4.2$	$24.6\pm4.3$	0.0 (-0.3 to 0.2)	0.0 (-0.3 to 0.3)
Body Fat (kg)	$23.7\pm6.9$	$23.1\pm7.1$	$24.0\pm7.4$	-0.6 (-1.7 to 0.4)	0.3 (-1.0 to 1.5)
Body Fat (%)	$36.5\pm5.7$	$36.0\pm5.9$	$36.9\pm5.8$	-0.5 (-1.4 to 0.4)	0.5 (-0.7 to 1.6)
Lean Mass (kg)	$40.0\pm5.1$	$39.8\pm4.7$	$39.9\pm5.3$	-0.2 (-0.7 to 0.4)	-0.1 (-0.8 to 0.5)
Lumbar Spine (L <sub>1</sub> -L <sub>4</sub> ) (T-score)*	$-1.9\pm0.9$	$-1.8 \pm 0.9$	$-1.8\pm0.9$	0.0 (-0.1 to 0.1)	0.0 (-0.1 to 0.2)
Hip total (T-score)	$-1.5 \pm 0.6$	$-1.4 \pm 0.6$	$-1.5 \pm 0.7$	0.1 (0.0 to 0.2) <sup><math>\dagger</math></sup>	0.0 (0.0 to 0.2)
Femur neck (T-score)	$-1.6 \pm 0.6$	$-1.6 \pm 0.6$	$-1.7 \pm 0.6$	0.00 (-0.08 to 0.13)	-0.01 (-0.13 to 0.04)
Femur trochanter (T-score)	$-1.5 \pm 0.6$	$-1.5 \pm 0.6$	$-1.6 \pm 0.7$	0.00 (-0.15 to 0.20)	-0.01 (-0.22 to 0.11)
Lumbar Spine (L <sub>1</sub> -L <sub>4</sub> ) (BMD g/cm <sup>2</sup> )	$0.957\pm0.129$	$0.944 \pm 0.119$	$0.950\pm0.110$	-0.013 (-0.035 to 0.008)	-0.007 (-0.032 to 0.019)
Hip total (BMD g/cm <sup>2</sup> )	$0.813\pm0.083$	$0.825\pm0.085$	$0.821\pm0.088$	$0.012~(\text{-}0.042~\text{to}~0.033)^\dagger$	0.008 (-0.047 to 0.036)
Femur neck (BMD g/cm <sup>2</sup> )	$0.790\pm0.084$	$0.799\pm0.089$	$0.793 \pm 0.081$	0.009 (-0.005 to 0.020)	0.003 (-0.010 to 0.018)
Femur trochanter (BMD g/cm <sup>2</sup> )	$0.646\pm0.071$	$0.665 \pm 0.076$	$0.654 \pm 0.085$	$0.019~(0.007~{ m to}~0.032)^{\dagger}$	0.008 (-0.010 to 0.027)

Data are presented as mean and SD, CI=Confidence Interval BMI=body mass index, \*T-score=number of standard deviations below the mean of a healthy, young sex matched population 

BMD=bone mineral density <sup>†</sup>p-value <0.05 

#### TABLE 4: Physical capacity, Borg scale, physical activity level and dynamic balance from pre- to post-intervention, and from pre-intervention to 1-year follow-up (n=31)

				Change from pre-	Change from pre-
				intervention to post- intervention	intervention to 1
	Pre-intervention	Post-intervention	1 year	Mean (95% CI)	year Mean (95% CI)
FSST (sec)*	9.5 ± 5.0	8.6 ± 3.6	$7.9 \pm 2.5$	-0.9 (-1.7 to 0.3)	-1.6 (-3.1 to -0.09)†
6 MWT (m)*	594 ± 81.7	611 <b>±</b> 94	599 ± 87.3	17 (-16.0 to 50.1)	5 (-27.9 to 37.9)
Borg scale <sup>*</sup>	$10.1\pm2.2$	$10.6\pm2.8$	$10.7\pm2.3$	0.6 (-0.7 to 1.9)	0.6 (-0.47 to 1.8)
PASE (0-315)	$108.9\pm58.9$	$124.5\pm62.1$	$129.1\pm60.6$	15.6 (-12.0 to 43.4)	20.2 (-0.63 to 41.1)

FSST=Four Square Step Test, 6 MWT=Six Minute Walk Test, PASE=Physical Activity Scale for the Elderly \*n=30 at post-intervention, one participant was not tested due to fracture in left ankle

<sup>†</sup>*p*-value < 0.05

23

				Change from pre-	Change from pre-
				intervention to post-	intervention to 1 year
				intervention	
	<b>Pre-intervention</b>	Post-intervention	1 year	Change (95% CI)	Change (95% CI)
Physical functioning	$83.2\pm18.7$	$84.3\pm18.8$	$84.5\pm14.1$	1.1 (-3.4 to 5.7)	1.3 (-6.1 to 8.7)
Role limitations-physical	$72.9\pm30.9$	$82.2\pm26.2$	$83.8\pm21.5$	9.3 (-1.1 to 19.7)	10.9 (-1.9 to 23.7)
Bodily pain	$71.3\pm23.7$	$76.7\pm24.2$	$74.9\pm22.5$	5.4 (-3.1 to 14.1)	3.6 (-5.6 to 12.8)
General health perceptions	$74.0\pm18.0$	$71.9\pm22.8$	$72.7\pm20.8$	-2.1 (-9.4 to 5.1)	-1.3 (-6.9 to 4.4)
Vitality	$58.8\pm21.6$	$63.5\pm19.0$	$62.7 \pm 18.8$	4.7 (-1.6 to 10.9)	3.9 (-2.4 to 10.1)
Social functioning	$82.6\pm22.2$	$85.0\pm22.4$	$90.3 \pm 15.0$	2.4 (-3.7 to 8.5)	7.7 (-0.9 to 16.3)
Role limitations-emotional	$87.9 \pm 19.8$	$89.7 \pm 19.8$	$90.3 \pm 19.6$	1.8 (-5.5 to 9.3)	2.4 (-3.4 to 8.2)
Mental health	$79.1 \pm 14.0$	$80.1\pm16.2$	$81.7 \pm 13.3$	0.9 (-5.0 to 7.0)	2.6 (-1.4 to 6.5)

**TABLE 5:** SF-36 subscales (0-100) from pre- to post-intervention, and from pre-intervention to 1-year follow-up (n=31) 

Data are presented as mean and SD, CI=Confidence Interval, SRM=standardized response mean SF-36=Short Form 36

28 29

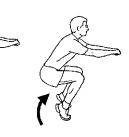
33	APPENDIX	ONLINE
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- 34 Copyright © 2012 by ExorLive AS
- 35 Active rehabilitation program with examples of some exercises
- 36 Exercises during warm-up period (10 minutes)
- Walking
- 38 Arm swing
- Knee lift with and without arms
- 40 Squats
- 41 Squats while walking
- 42 Exercises during flexibility period (hold each stretch for 30 seconds) (3 minutes)
- 43 Hip flexion
- Quadriceps stretch
- 45 Lateral lunge
- 46 Exercises for strength, balance, core stability, and use of weight-vest (40 minutes)
- 47 *Lower extremities muscle strengthening exercises (12 minutes)*
- 48 Squats (FIGURE A1)
- Squats with lifting the feet
- 50 Squats with lifting the heel (**FIGURE A2**)
- Forward lunges (FIGURE A3)
- 52 Progression
- Step-up/step-down (FIGURE A4)
- Squats with weight-vest (FIGURE A5)
- Forward lunges with weight-vest (FIGURE A6)
- 56 Step-up/step-down with weight-vest





A1



A2

A6





A4



59 A5

- 60
- 61 Balance (12 minutes)
- 62 Semi-tandem stance
- Single-leg stance (FIGURE A7)
- 64 Progression
- Single-leg stance with squat (FIGURE A8)
- Single-leg stance. Raising one leg by forming a figure of 8 (FIGURE A9)
- Step-up/step-down with a leg lift (FIGURE A10)
- Step-up/step-down with a leg lift with weight-vest (FIGURE A11)
- Single-leg stance on gym mat (FIGURE A12)
- Squats leading one leg back- and forward on gym mat
- Two participants standing on 2- or 1-leg: throwing ball to each other on gym mat
   (FIGURE A13)
- Single-leg stance resting the other leg on a fitness ball and moving the ball from side
   to side (FIGURE A14)



A7



A8

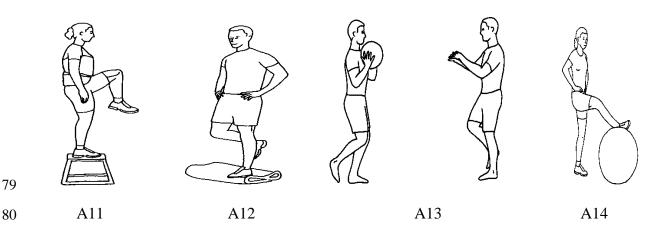


A9



A10

75 76 77



- 81
- 82 Upper extremities muscle strengthening exercises (6 minutes)
- Standing 1-arm biceps curl (FIGURE A15)
- Standing both arms biceps curl (FIGURE A16)
- Standing 1-arm triceps curl (FIGURE A17)
- Standing arm stretched side lift curl (FIGURE A18)

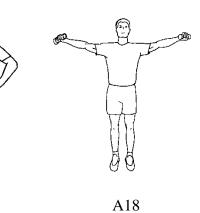
- Sitting on a fitness ball biceps curl (FIGURE A19)
- Sitting on a fitness ball triceps curl (FIGURE A20)
- Sitting on a fitness ball stretched side lift curl (**FIGURE A21**)
- 91

<sup>87</sup> Progression



A15





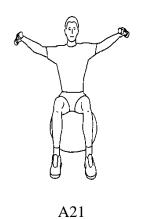
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A19





A17

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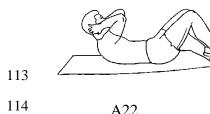
98 *Trunk/Core strengthening exercises (10 minutes)* 

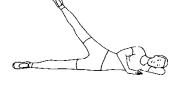
- 99 Crunches (FIGURE A22)
- Side-lying plank 1-leg (FIGURE A23)
- Side-lying plank 2-legs (FIGURE A24)
- 102 Bridging 2-legs (FIGURE A25)
- 103 Bridging 1-leg (FIGURE A26)
- Back lift lying face down (FIGURE A27)
- Back lift with arm swing lying face down (FIGURE A28)
- Back lift with stretching the opposed leg and arm lying face down (FIGURE A29)

107

#### 109 Progression

- Side-lying plank scissoring with the legs (FIGURE A30) 110 •
- Sitting on a fitness ball and move from side to side (FIGURE A31) 111 •
- 112





A23







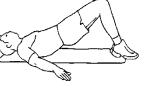
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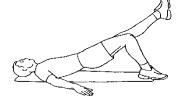
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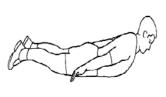
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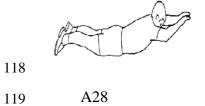






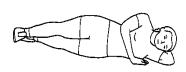
A26

A27





A29



A30

120



122 A31

- 123
- 124

- 126 Cool-down and flexibility (7 minutes)
- Walking in a big circle
- Flexibility exercises for the major muscle groups