**TITLE:** The Effects of Home Exercise in Older Women With Vertebral Fractures: A Pilot Randomized Controlled Trial

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**Background:** Regular exercise is advocated in osteoporosis guidelines to prevent fractures. Few studies have evaluated the effect of exercise on functional performance, posture and other outcomes that are important to patients after vertebral fractures.

**Objective:** This pilot study will explore the effect of home exercise versus control on functional performance, posture, and patient-reported outcome measures.

**Design:** This study was a parallel two-arm pilot feasibility trial with 1:1 randomization to exercise or attentional control groups.

**Setting:** This study took place in 5 Canadian and 2 Australian academic or community hospitals/centers.

**Participants:** This study included 141 women ≥65 years with radiographically confirmed vertebral fractures.

**Intervention:** A physical therapist delivered exercise and behavioral counseling in 6 home visits over 8 months and monthly calls. Participants were to exercise ≥3 times weekly. Controls received equal attention.

**Measurements:** Functional performance, posture, quality of life, pain and behavior-change outcomes were assessed at baseline and after 6 and 12 months. Adherence to exercise was assessed by calendar diary. T-tests examined between-group mean differences (MD) in change from baseline in intention-to-treat (ITT) and per-protocol analyses.

**Results:** There was a small effect of exercise on five times sit-to-stand test versus control (MD: -1.58 [95% CI: -3.09, -0.07], ITT; MD: -1.49 [95% CI: -3.12, 0.16], per-protocol). There were no other major or statistically significant MDs for any other measured outcomes after follow-up. Adherence declined over time.

**Limitations:** Treatment effects on variables may have been underestimated due to multiple comparisons and underpowered analyses.

**Conclusions:** Our exploratory estimate of the effect of exercise on functional leg muscle strength was consistent in direction and magnitude with other trials in individuals with vertebral fractures. Declining adherence to home exercise suggests that strategies to enhance long-term adherence might be important in future confirmatory trials.

Osteoporotic vertebral fractures are associated with significant health and economic burden worldwide1,2 and can lead to functional decline,3 pain,4 reduced quality of life,5 hospitalization,6 and even death.7 Prevalent vertebral fractures are reported in up to 25% of postmenopausal women,8-10 with an absolute risk of incident vertebral fracture of 50% versus 9% among women with no vertebral fracture and normal bone mineral density (BMD).11 Regular exercise is advocated in osteoporosis guidelines to prevent falls and fragility fractures.12 Exercise recommendations were recently established for individuals with osteoporosis and vertebral fractures using the GRADE approach,13,14 and emphasized progressive resistance, balance and postural training. Recent calls for a large randomized controlled trial (RCT) to evaluate the effect of exercise on fracture risk have been met with considerable challenges, including the large sample size required, need for multiple enrolling sites, and high resource burden.15,16 Consequently, there is limited evidence on the effect of exercise on outcomes that are important to patients (e.g., functional performance, quality of life, pain) after vertebral fracture.17

Substantial evidence exists in support of the therapeutic benefits of exercise on surrogate outcomes for fracture risk (e.g., BMD, falls) in older adults18,19 and postmenopausal women.20 Meta-analysis results suggest that challenging balance training can prevent falls in community-dwelling older adults by 21% to 39%.19 Yet, the effect of exercise on BMD varies by type of training.20 Low-force dynamic exercise, progressive resistance training, or combined programs can positively influence spine BMD;20 while, high-force dynamic exercise, progressive resistance training, or combined programs have a significant effect on hip BMD.20 However, few studies have examined the efficacy and safety of exercise to improve outcomes after vertebral fracture.17,21 Individuals with vertebral fractures require tailored exercise prescription, especially in the presence of pain, hyperkyphosis, and mobility limitations.22 In a recently-updated Cochrane review of nine exercise trials in individuals with vertebral fractures,21,23 the effects of exercise on performance-based mobility outcomes were promising, but the magnitude of the effect on Timed Up and Go (TUG) (mean difference (MD) between intervention and control groups: -1.09 seconds, 95% CI: -1.78, -0.40) and maximum walking speed (MD: -1.90 seconds, 95% CI: -3.05, -0.75) were small and did not represent clinically important differences.21,24-26 Modest effects on pain,26,27 quality of life24,28,29 and fear of falling30 have also been observed in older adults with vertebral fractures after exercise intervention. These results should be interpreted with caution as other studies have reported no significant effects of exercise on TUG,26,29 balance,29,31 pain,25,32 posture26,28,33 and health-related quality of life.24,26

Research on the effects of exercise on functional, health and behavioral outcomes after vertebral fracture is scarce and current evidence is limited by study bias, sample size and short duration follow-up.21,23 A high-quality trial is needed to examine the potential efficacy and safety of exercise in individuals with vertebral fractures. Furthermore, many previously published exercise interventions are centre-based and supervised by a physical therapist,21,23 however, many patients would not have access to a supervised environment long-term, or at all. Health care providers who prescribe exercise to individuals with vertebral fractures need evidence-based trials that test interventions that are realistic to deliver in practice. The Build Better Bones with Exercise (B3E) pilot trial was designed to determine the feasibility of an RCT of home exercise delivery with incident fragility fracture as a primary endpoint in individuals with vertebral fractures34 and the feasibility results have been published elsewhere.35 The objective of the present exploratory analysis was to report on the estimated effects and variability of the effects of home exercise versus control on functional performance, posture and patient-reported outcome measures.

**[H1] Methods**

**[H2] *Study Design***

Exploratory analyses of secondary outcomes from a pilot multicenter single-blinded parallel RCT (B3E pilot trial) were conducted; the protocol and feasibility results have been previously published (ClinicalTrials.gov NCT01761084).34,35 The study and intervention protocols were drafted according to the CONSORT guidelines for randomized pilot and feasibility studies,36-38 SPIRIT 2013 statement39 and TIDieR checklist.40 Research ethics committee approval was obtained at each enrolling site. All study sites received a written study protocol and in-person or teleconference training by the coordinating center. Seven centers in Canada and Australia enrolled community-dwelling women ≥65 years with ≥1 radiographically-confirmed vertebral compression fracture of Genant Grade 2 or higher.41 Recruitment was conducted through primary care or specialist osteoporosis clinics, and to a lesser extent through the Canadian Osteoporosis Patient Network or other mailing lists. Participants were randomized 1:1 via computer algorithm, using permuted block sizes of two or four, into the home exercise or an equal-attention control group.

The home exercise intervention has been described previously.34 Both groups received six home visits from a PT over 8 months (4 visits in Months 1-2 and one visit each after 6 and 8 months) and bi-weekly phone calls in Months 1 to 2 and thereafter monthly phone calls from a physical therapist and blinded research assistant (RA). The intervention group received instruction on exercise and the control group discussed general health-related topics (excluding exercise). Baseline and follow-up assessments after 6 (questionnaires only) and 12 months were completed by a blinded RA at a research facility, and home visits occasionally as necessary. To limit unblinding of site RAs, physical activity questionnaires were conducted by an unblinded RA who was not involved in participant recruitment or assessments.

**[H2] *Participants***

The inclusion criteria were: 1) women; 2) ≥65 years of age; and 3) radiographic evidence of ≥25% reduction in anterior, middle, or posterior height of at least one vertebra between T4 and L4, centrally-adjudicated by the study radiologist from X-rays using the Genant method.41 Exclusion criteria included: 1) an index vertebral fracture due to trauma; 2) any medical disorder likely to prevent study completion or exercise participation; 3) exercise participation ≥3 times/week that addresses ≥2 of 5 domains in the exercise prescription; 4) impaired capacity to give informed consent or communicate in English; 5) unable to stand or walk 10 meters with or without a gait aid; 6) history of cancer in the past five years (excluding basal cell carcinoma); or 7) exercise contraindications as determined by a physician.42 The Mini-Cog was used to screen for cognitive impairment and determine capacity to consent.43 Lateral thoracic and lumbar spine X-rays were centrally-adjudicated by the study radiologist to confirm the presence of at least one Genant Grade 2 or higher vertebral compression fracture. The short-form International Physical Activity Questionnaire (IPAQ) assessed physical activity levels.44 All participants gave informed, written consent prior to study enrolment.

**[H2] *Intervention/Control Activities***

The intervention group received home exercise from the study physical therapist .34 Each site had at least one certified physical therapist and we attempted to have participants work with the same PT throughout the study. At sites that had more than one physical therapist, allocation was determined by proximity to the participant, caseload, and any modifying factors (e.g., pet allergies). The exercise program was individually tailored to the participant (training dosage and progression) and consisted of ≥1 exercise from each of following domains: upper-body strength (e.g., wall/floor push-up, tubing pulldown, upright row), lower-body strength (e.g., sit-to-stand or squat, lunge, step-up), posture/core strength (planks, thoracic/lumbar extension using bird-dog, or in supine), and balance training (single-leg balance, tandem stance or tandem walk). Physical therapists were instructed to prescribe a minimum of 5 to 8 exercises to start, and a minimum of 2 sets of 8 to 10 repetitions maximum (or isometric holds for 3-5 seconds if applicable), and progressively increase the volume or intensity over time. The target exercise prescription was at least thrice-weekly resistance exercises at 8 to 12 repetitions maximum and daily aerobic physical activity (10 to 30 minutes per day), balance and posture exercises.34 The Motivation to Move behavior-change program was used to enhance adherence and involved motivational interviewing45,46 and the Health Action Process Approach.47 Exercise frequency, intensity and duration were progressed by the PT during the home visits and phone calls.42 Control participants received the same number and duration of home visits and calls from the physical therapist, which focused on general health or social discussion. Control topics were tailored to the participant but excluded exercise. Adherence was defined as the completion of strength and balance exercises ≥3 days per each complete 7-day period in their daily diaries (per-protocol approach). The *a priori* criterion for success was defined as at least 60% adherence to strength and balance exercises thrice-weekly.34 All participants received vitamin D and were instructed to take 1,000 IU daily (Ddrops-Woodbridge, ON, Canada and Swisse Wellness-Melbourne, Australia). Individuals prescribed a higher daily dose by a physician continued that dosage.

**[H2] *Outcome Measures***

**[H3] *Functional Performance and Posture Outcomes***

Functional performance was measured using the validated Short Physical Performance Battery (SPPB)48 and Balance Outcome Measure for Elder Rehabilitation (BOOMER).49,50 The SPPB includes the 4-meter walk test; timed static stance tests in feet together, semi-tandem and tandem positions with eyes open;48 and five times sit-to-stand (5T-STS) test.51 The BOOMER includes the TUG test;52 functional reach test;53 timed static stance test in feet together position with eyes closed;49 and step test.49 The composite scores on the SPPB (0-12) and BOOMER (0-16) were reported along with the separate test results in their absolute units. An SPPB score of ≤9 is indicative of physical limitations and higher risk of major mobility disability.54 All individual tests are reliable and valid measures of functional strength, mobility and balance in older adult populations.49,51-53,55

The 4-meter walk test measures the time taken to walk at a usual speed over a 4-meter course, and the fastest time of two trials was reported.48 The 5T-STS test measures the time taken to rise from a chair with arms folded across the chest and sit back down five times consecutively.56 The TUG test measures the time taken to rise from a chair, walk 3 meters, then walk back and return to a seated chair position.52 If the 5T-STS or TUG test were not completed as instructed in the first trial, the test could be repeated and the fastest time was reported. Static balance tests were timed and performed unassisted without shoes in one trial only. The functional reach test measures the maximum distance that an individual can reach forward with the dominant arm while standing in a fixed position without shoes.53 Participants were allowed up to 2 practice trials before the result was recorded. The step test measures the number of completed steps without shoes in trials of 15 seconds, measured for each foot stepping separately. The average number of steps between the right leg stepping and left leg stepping was reported.49 Trunk muscle extensor endurance was measured using the Timed Loaded Standing (TLS) in a subset of 34 participants at two study sites to minimize participant and study personnel burden.57 The TLS is a reliable and valid measure of combined trunk and arm muscle endurance.57,58 The TLS measures the time a person can stand while holding a 0.91 kg (2 lb) dumbbell in each hand with their arms at 90 degrees of shoulder flexion, and elbows extended and mid-prone up to two minutes maximum.

Occiput-to-wall distance was calculated as the horizontal distance to the nearest 0.1 centimeter from the bony prominence of C7 to the wall using a ruler.59 Occiput-to-wall distance has a strong correlation (r= 0.902) with the Flexicurve kyphosis measure indicating concurrent validity to measure forward head posture and hyperkyphosis.59 Standing height was measured without shoes and at the end of a normal expiration using a calibrated stadiometer or measuring tape mounted on a wall to the nearest 0.1 centimeter.

**[H3] *Quality of Life, Pain and Behavioral Outcomes***

The EQ5D-3L questionnaire assessed health-related quality of life and morbidity with the self-perceived health rating (0-100) visual analogue scale (VAS) multiplied by mortality to calculate a quality-adjusted life-year estimate (health utilities index or HUI).60 Evidence of construct validity and test-retest reliability for the EQ5D-3L has been shown.60 The mini-Osteoporosis Quality of Life Questionnaire (mini-OQLQ) was used to measure quality of life specific to osteoporosis, and is a valid measure in individuals with vertebral fractures.61,62 The mini-OQLQ subscale scores (symptoms, physical function, activities of daily living, emotional function, leisure) were reported. Pain was measured using VAS ratings (0-10) at rest and during movement in the past week. Fear of falling was assessed using the Short-Form Falls Efficacy Scale International (FES-I).63 The Short-Form FES-I asks participants about how concerned they are about the possibility of falling while completing certain activities (1=not at all concerned; 2=somewhat concerned; 3= fairly concerned; 4=very concerned).41 An exercise self-efficacy questionnaire assessed action, intention and coping planning and overall exercise self-efficacy using 5-point categorical scoring (1=not at all true; 2=barely true; 3=unsure; 4=mostly true; 5=exactly true)64 and was informed by the Health Action Process Approach.47

**[H3] *Descriptive Outcomes and Vertebral Fracture Ascertainment***

Past and current medication use, demographic and lifestyle characteristics were obtained via an interviewer-assisted medical history and health status questionnaire. Data on vertebral fracture history, calcium/vitamin D supplementation, osteoporosis medication, glucocorticoid use, and history of co-morbidities were collected. Lumbar and thoracic spine X-rays were conducted at local diagnostic imaging clinics or hospitals at baseline and after 12 months. Vertebral fractures were defined as radiographic presence of ≥25% reduction in anterior, middle, or posterior height of a vertebra, centrally-adjudicated by the study radiologist from X-rays using the Genant method.41 All participants were instructed to complete daily diaries to record physical activity and health-related events (falls, fractures, adverse events). Fractures, falls, adverse events and primary feasibility outcomes are reported elsewhere.35 Weight was measured without shoes, jewellery or any heavy clothing using a calibrated electronic scale to the nearest 0.1 kilogram.

**[H2] *Data Management and Statistical Analysis***

Data management procedures are described elsewhere.35 In brief, each study site had a coordinating research assistant to manage the trial, obtain consent and perform assessments and analyses. Data analysts were blinded to group allocation. Reporting of outcomes was in accordance with CONSORT 2010 extension for randomized pilot and feasibility trials.36 Descriptive characteristics and study outcomes were summarized using mean (standard deviation, SD) or median (interquartile range, IQR) for continuous variables and number (%) for categorical variables. Change in functional performance tests, posture, quality of life, pain and behavior-change outcomes after 6 and 12 months were reported as absolute change values and analyzed as mean between-group differences (MD) and 95% confidence intervals (95% CI) using *t* tests. Per-protocol and intention-to-treat (ITT) analyses of all outcomes were conducted. Post-hoc sensitivity analyses adjusting for baseline values in general linear models (analysis of covariance) were performed to compare mean change from baseline between-groups for each outcome.Another sensitivity analysis was conducted on the adherence data, where weekly adherence was calculated per participant for months 1 to 11 due to reduced response rate during month 12, including weeks with enough data to infer adherence or lack of adherence (per-diary approach).35 Subgroup analyses compared outcomes in the participants with ≥80% adherence to the intervention versus control participants. We did not stratify analyses by study site since randomization was stratified by site and any variability between exercise and control groups across sites would be balanced. Missing values analysis was conducted to analyze patterns of missing data. Multiple imputation procedures were used to impute the missing data values (fully conditional specification method, model for scale variables=linear regression, number of imputations=5, maximum iterations=25) and pooled results were reported. No corrections for multiple testing or sample size calculations were performed because of the exploratory nature of the analyses. No participants opted to withdraw their data following withdrawal from the study. All statistical analyses were conducted using SPSS Statistics v.24 (Armonk, NY, USA).

**[H2] ROLE OF THE FUNDING SOURCE**

The authors certify that no party having a direct interest in the results of the research supporting this article has or will confer a benefit on them or on any organization with which they are associated. The authors also certify that all financial and material support for this research and work are clearly identified in the acknowledgments.

**[H1] Results**

**[H2] *Study Recruitment and Retention***

2822 individuals were screened for eligibility, mostly at specialist clinics or primary care practices (Fig. 1). Of these, 180 passed screening and 176 consented to participate. Twenty participants failed the Mini-Cog but could recall relevant details about the study and so were included, though one withdrew prior to randomization for other reasons. Sixteen consenting participants did not complete a baseline assessment or randomization (no qualifying fracture on X-ray, n = 11; withdrew consent due to change in health status, n = 5). Of the 160 individuals who completed the baseline assessment, 19 were deemed ineligible (no qualifying fracture on X-ray, n = 13; failed the Mini-Cog and were unable to correctly answer questions about the study, n = 2;withdrew consent prior to randomization, n = 3; ankle fracture prior to randomization, n = 1). A total of 141 participants were randomized to intervention (n = 71) and control groups (n = 70).

Nine participants withdrew consent (5 intervention; 4 control), and 2 (both controls) had a change in health status and subsequently withdrew from the trial (1 experienced marked cognitive decline and the other developed a cardiac condition and was referred to a cardiac rehab program involving exercise by her physician) (Fig. 1).

**[H2] *Descriptive Characteristics***

The mean (SD) age of participants was 76 (6) years in the intervention group and 77 (7) years in the control group(Tab. 1). Participants reported a mean (SD) of 44 (144) minutes/week of moderate-to-vigorous physical activity and 6 (16) minutes/week of strength/balance physical activity. The median (IQR) number of vertebral fractures was 2 (2) and 67% of participants had at least one grade 3 vertebral fracture confirmed by X-ray adjudication. The median (IQR) number of falls in the past year was 0 (1). Forty-nine percent of participants demonstrated an SPPB score >9 and 61% reported ≥75 for EQ5D VAS self-perceived health status.

The overall adherence to the home exercise program was 66% (per-protocol approach), meeting our *a priori* criteria of 60% adherence to thrice-weekly strength and balance exercise. Average adherence to home exercise over months 1 to 11 was 73%; yet, adherence declined from 82% at month 3 to 68% at month 6 and 59% at month 11 (per-diary approach). Twenty percent of control participants reported doing strength/balance exercises ≥3 times/week during follow-up. There was a significant between-group difference in strength and balance physical activity after 6 (MD: -65.9 minutes/week, 95% CI: -91.8, -40.0) and 12 months (MD: -49.3 minutes/week, 95% CI: -69.8, -28.8). No other IPAQ outcomes significantly differed between groups at either timepoint.

**[H2] *Change in Functional Performance and Posture Outcomes***

A small between-group difference in 5T-STS test time was observed in favor of exercise (MD: -1.58 seconds, 95% CI: -3.09, -0.07, ITT; MD: -1.48 seconds, 95% CI: -3.13, 0.16, per-protocol) (Fig.2A); which remained statistically significant after adjusting for baseline values (MD: -1.60 seconds, 95% CI: -2.88, -0.31). There were no significant between-group differences for the other SPPB outcomes in the ITT and per-protocol analyses, even after adjusting for baseline values (Tab. 3). While there were no significant between-group differences for the overall BOOMER score over time, there were non-statistically significant changes in the direction of improvement within the intervention group for several of the individual BOOMER components (Fig. 2B-D and Tab. 3). There was no between-group difference in TLS (MD: -0.08 seconds, 95% CI: -31.5, 31.7, per-protocol). Further, there were no statistically significant effects of exercise on posture (Tab. 3).

**[H2] *Change in Quality of Life, Pain and Behavioral Outcomes***

There were no statistically significant between-group differences for EQ5D-3L, mini-OQLQ, pain and fear of falling outcomes at either timepoint even after adjusting for baseline values (Tab. 4) (Supplemental Table 1 https://academic.oup.com/ptj). Yet, EQ5D HUI score improved in the intervention group relative to the control group after 6 months (MD: 0.050 points, 95% CI: 0.001, 0.098), but not after 12 months, once baseline values were adjusted for. Coping planning improved in the intervention versus control group after 6 months in the ITT (MD: -0.73 points, 95% CI: -1.40, -0.06) and per-protocol analyses (Tab. 4) but was no longer significant at 12 months (adjusted and unadjusted for baseline values).There were no other statistically significant between-group differences in exercise self-efficacy outcomes at follow-up in the unadjusted analyses. However, after adjusting for baseline values, action planning (MD: 0.89 points, 95% CI: 0.47, 1.32 after 6 months and MD: 0.60 points, 95% CI: 0.16, 1.04 after 12 months) and intention planning (MD: 0.81 points, 95% CI: 0.32, 1.30 after 6 months and MD: 0.59 points, 95% CI: 0.07, 1.11 after 12 months) improved in the intervention group relative to the control group at both timepoints.

**[H2] *Comparisons Between Adherent Participants Versus Controls***

Comparisons between adherent participants (≥80% adherence) versus controls revealed no statistically significant between-group differences for any of the measured outcomes.

**[H1] Discussion**

Our exploratory findings demonstrate a small effect in favor of exercise on functional leg muscle strength, which is consistent in direction and magnitude to changes in functional performance outcomes in other exercise trials in individuals with vertebral fractures.21,23 The lack of clinically significant effects of exercise on functional performance, quality of life and other measured outcomes may be due to declining adherence to home exercise, control group contamination, and variability in the estimates. Modest within-group improvements in TUG, step test, pain at rest, disease-specific quality of life, fear of falling and coping/intention planning were observed following exercise. Although intermittently supervised home exercise is often recommended as a more feasible or less costly option, it may not engender long-term adherence or large changes in patient-reported outcome measures. Future trials in individuals at high-risk of fracture may need to consider continuously supervised exercise or other behaviour change strategies to enhance adherence and ensure adequate intensity and progression.

Home exercise was associated with a small improvement in 5T-STS from 15 seconds (indicative of greater disability/morbidity)65 to 13 seconds (more consistent with normative values).66 Meretta et al.56 reported a minimal clinically important difference for 5T-STS (2.3 seconds) in older adults with vestibular disorders. Therefore, our results may reflect a clinically important change secondary to progressive multicomponent exercise. These data must be interpreted with caution due to multiple testing of functional performance variables as well some participants were unable to complete the 5T-STS (12%), suggesting potential floor effects for this measure. We did not find any clinically or statistically significant between-group differences for the TUG, 4-meter walk and other functional tests. These findings align with Cochrane evidence reporting modest but not clinically-important exercise-related improvements in TUG24-26 and maximum walking speed24 in individuals with vertebral fractures. Supervised high-intensity resistance and impact exercise may be more effective in improving functional performance in more physically capable older women with low bone mass.67 However, it is unclear whether this training approach is safe and effective in those with multiple vertebral fractures. An increase in control group MVPA (~85 minutes/week) may have influenced our results and 20% of control participants reported some resistance and balance exercise during follow-up despite being randomized to control. Substantial ceiling effects (52% had BOOMER score ≥14) and non-normal score distributions have been reported elsewhere50, especially the composite score and static balance test, and could have affected responsiveness. It is also possible that the sample size was not enough considering the heterogeneity of this high-risk group, particularly for the analysis of the Timed Loaded Standing test results which was performed in a subset of 34 participants.

Postural changes including kyphosis and height loss are often severe after vertebral fracture.68 Hyperkyphosis may also increase the risk of future vertebral fractures.69 Occiput-to-wall distance is often used as an indicator of forward head posture and a surrogate measure of hyperkyphosis.12,70 Both intervention and control groups had a mean occiput-to-wall distance >5 cm, reflective of at least one Genant Grade 2 vertebral fracture and mild-to-severe hyperkyphosis.71 However, we did not observe any effect of exercise on occiput-to-wall distance consistent with other trials in individuals with vertebral fractures.26,28,33 Benedetti et al.72 found a 1.4-cm decrease in occiput-to-wall distance following 12 weeks of postural training in older adults with flexed posture, which is likely more reflective of a clinically meaningful change. Bennell et al.26 reported a reduction (5%) in inclinometer-measured thoracic kyphosis after 10 weeks of exercise and manual therapy in older women with vertebral fractures, likely due to the small sample size and shorter-duration intervention.26 Occiput-to-wall distance may not be sensitive enough to capture subtle postural changes following exercise intervention. Future trials in individuals with vertebral fractures might consider using higher intensity spine-strengthening exercises73 and validated, precise postural measures (e.g., Flexicurve, kyphometer).

In the present study, there were no major or statistically significant improvements in quality of life, pain or behaviour-change questionnaires after 6 and 12 months of home exercise. Prior RCTs of exercise in individuals with vertebral fractures present low-quality, inconsistent evidence across quality of life subscales (QUALEFFO-41, OQLQ),24,26,28,29 with positive effects observed after more than 6 months of exercise.24,28 Papaioannou et al.29 found improvements in the symptoms, emotion, and leisure/social subscales from the disease-specific OQLQ after 6 months of home exercise in older women with vertebral fractures, but only the symptoms subscale remained significant after 12 months. Evstigneeva et al.28 and Bergland et al.24 reported between-group differences in QUALEFFO-41 total score after 12 months of supervised center-based exercise. Pain and fear of falling are well-known consequences of vertebral fractures that may affect quality of life,7 and are often targets of rehabilitation in these high-risk individuals. Prior research indicates an effect of exercise on pain after vertebral fracture in those reporting pain at baseline (clinically meaningful improvements of >1-point or 15% change).26,27,32 We did not find any exercise-related effects on pain in our participants with lower baseline pain levels (mean resting pain VAS=2.5). Olsen and Bergland30 found an effect of exercise on fear of falling in women with vertebral fractures; while our study found no clinically-important differences using the short-form FES-I.If pain and fear of falling were outcomes of importance, a trial should aim to recruit individuals with pain or a history of falling at baseline, and our trial did not require the presence of either. Home exercise with behavior change counseling was associated with small improvements in action, coping and intention planning after 6 months, yet this effect was minor or no longer statistically significant after 12 months, likely coinciding with declines in supervision and adherence.

Strengths of the present study include the evidence-based exercise prescription, use of behavior-change techniques,46,47 multicenter RCT design, excellent retention rates, and blinded outcome assessment. The study has several limitations. Since the primary outcome of our study was feasibility of a multicenter trial with an incident fragility fracture outcome,35 our findings are largely exploratory and likely influenced by multiple comparisons (potential likelihood of false negative results) and a small sample size (underpowered analyses). However, our study is among the largest in this population to date.Due to the intervention design, it was not possible to blind participants to group allocation, which may have affected outcome responsiveness, especially for self-report measures. Participants could seek exercise instruction elsewhere with 20% of control participants reporting balance and resistance exercise during follow-up. We used a pragmatic model of home exercise delivery comparable to existing home care models; six home visits by a physical therapist with follow-up phone calls. This approach may not be enough to ensure adequate intensity and progression or promote long-term adherence. Many trials examine short-term effects of exercise, whereas our intention was to examine whether home exercise prescription had long-term effects. These limitations may have affected the potential to elicit changes in functional performance, behaviors and other outcomes.

In conclusion, our exploratory estimate of the effect of home exercise on functional leg muscle strength was consistent in direction and magnitude to the observed effects of exercise on functional/mobility outcomes in other trials in individuals with vertebral fractures. However, important treatment effects on other variables may have been underestimated in this pilot trial due to key study limitations, including the risk of false negative results related to multiple comparisons and underpowered analyses. Declining adherence to the home exercise program suggests that the incorporation of behaviour change strategies to enhance long-term exercise self-efficacy in addition to more supervision might be important in future exercise interventions in women with vertebral fractures. Further research is needed to explore factors influencing adherence and the efficacy of exercise to improve functional performance, posture and patient-reported outcome measures in individuals at high-risk of fracture.

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**Ethics Approval**

Research ethics committee approval was obtained at each enrolling site. All study sites received a written study protocol and in-person or teleconference training by the coordinating center. All participants gave informed, written consent prior to study enrollment.

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**Clinical Trial or Systematic Review Registration**

This trial was registered on ClinicalTrials.gov (NCT01761084).

**Disclosure and Presentations**

The authors completed the ICMJE Form for Disclosure of Potential Conflicts of Interest and reported no conflicts of interest. The authors certify that no party having a direct interest in the results of the research supporting this article has or will confer a benefit on them or on any organization with which they are associated, and they certify that all financial and material support for this research and work are clearly identified in the acknowledgments.

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**Table 1.** Descriptive Characteristicsa

|  |  |  |
| --- | --- | --- |
| **Characteristic** | **Exercise Group**  **(n = 71)** | **Control Group**  **(n = 70)** |
| Age (y): Mean (SD) | 76.4 (6.4) | 77.0 (7.3) |
| Height (cm): Mean (SD) | 156.5 (6.2) | 156.3 (7.1) |
| Weight (kg): Mean (SD) | 65.1 (12.8) | 66.5 (15.4) |
| Body mass index (kg/m2): Mean (SD) | 26.6 (5.0) | 27.2 (5.9) |
| Number of vertebral fractures: Median (IQR) | 2.0 (2.0) | 2.0 (2.0) |
| Number of falls in past year: Median (IQR) | 0.0 (1.0) | 0.0 (1.0) |
| Assistive device use: N (%) | 22 (31.0) | 25 (35.7) |
| History of rheumatoid arthritisb: N (%) | 2 (3.0) | 6 (9.0) |
| History of osteoarthritisb: N (%) | 37 (56.1) | 43 (64.2) |
| History of heart disease: N (%) | 15 (21.1) | 14 (20.0) |
| History of high blood pressure: N (%) | 36 (50.7) | 36 (51.4) |
| History of diabetes: N (%) | 3 (4.2) | 6 (8.6) |
| History of chest pain: N (%) | 2 (2.8) | 2 (2.9) |
| Osteoporosis medication useb: N (%) | 50 (70.4) | 49 (72.1) |
| Past oral prednisone use >3 months: N (%) | 2 (2.8) | 4 (5.7) |
| History of smoking ever: N (%) | 32 (45.1) | 34 (48.6) |
| Current alcohol consumption: N (%) | 38 (53.5) | 35 (50.0) |
| Current calcium supplementationc: N (%) | 47 (66.2) | 45 (64.3) |
| Current vitamin D supplementationc: N (%) | 67 (94.4) | 65 (92.9) |
| MVPA (min/wk)d: Mean (SD) | 43.2 (138.5) | 48.8 (156.1) |
| Strength/balance activity (min/wk)d: Mean (SD) | 6.7 (17.0) | 6.4 (16.8) |
| Light-intensity walking (min/wk)d: Mean (SD) | 168.8 (366.0) | 194.9 (278.3) |

aIQR = interquartile range; MVPA = moderate-to-vigorous physical activity; SD = standard deviation.

b8 (5.7%) were not sure what type of arthritis.

c2 (1.4%) had missing data for osteoporosis medication use; 1 (0.7%) for calcium and vitamin D supplementation; 4 (2.8%) for multivitamin supplementation.

dMissing data for physical activity outcomes – intervention group (n=4) and control group (n=9)

**Table 2.** Baseline Data in the Exercise Group (n = 71) and Control Group (n = 70)a

|  |  |  |
| --- | --- | --- |
| **Variableb** | **Exercise Group**  **(n = 71)** | **Control Group**  **(n = 70)** |
| SPPB | | |
| SPPB total score | 9.4 (2.4) | 8.7 (2.3) |
| 4-meter walk test (sec)c | 4.1 (1.2) | 4.5 (1.3) |
| Five times sit-to-stand test (sec)d | 14.8 (6.5) | 15.6 (4.9) |
| Timed stance tests (points) | 3.5 (1.0) | 3.1 (1.2) |
| BOOMER | | |
| BOOMER total score | 13.3 (2.2) | 13.2 (2.0) |
| Functional reach test (cm) | 25.5 (8.0) | 25.7 (7.0) |
| Step test (# of steps – left) | 12.2 (4.3) | 11.7 (4.1) |
| Step test (# of steps – right) | 12.0 (4.1) | 11.9 (3.9) |
| Timed up and go test (sec)e | 11.8 (4.2) | 12.2 (3.5) |
| Timed stance, eyes closed test (sec) | 86.8 (14.6) | 85.4 (15.7) |
| Timed loaded standing (sec)f | 85.6 (39.8) | 90.8 (34.6) |
| Posture | | |
| Occiput-to-wall distance (cm) | 5.3 (4.0) | 6.2 (4.7) |
| Standing height (cm) | 156.5 (6.2) | 156.3 (7.1) |
| Quality of Life | | |
| EQ5D VAS perceived health statusg | 74.2 (19.1) | 75.7 (20.0) |
| EQ5D health utilities index score | 0.8 (0.1) | 0.8 (0.1) |
| Mini-OQLQ symptoms score | 4.8 (1.5) | 4.8 (1.4) |
| Mini-OQLQ physical function score | 4.8 (1.8) | 5.1 (1.6) |
| Mini-OQLQ activities of daily living score | 5.1 (1.9) | 5.1 (1.7) |
| Mini-OQLQ emotional function score | 5.3 (1.6) | 5.4 (1.7) |
| Mini-OQLQ leisure score | 5.7 (1.5) | 5.8 (1.7) |
| VAS Pain | | |
| Pain at rest (0-10)g | 2.7 (2.7) | 2.4 (2.1) |
| Pain during movement (0-10)g | 3.8 (2.9) | 4.2 (2.6) |
| Fear of Falling | | |
| Short-form FES-I total scoreh | 12.1 (4.8) | 12.9 (5.6) |
| Exercise Self-Efficacy | | |
| Action planning | 3.4 (1.6) | 2.9 (1.6) |
| Coping planning | 1.8 (1.3) | 1.9 (1.4) |
| Intention planning | 3.2 (1.6) | 3.0 (1.6) |
| Exercise self-efficacy | 4.4 (0.7) | 4.4 (0.6) |

aAll data expressed as mean (standard deviation, SD).

bADL = activities of daily living; BOOMER = Balance Outcome Measurement in Elder Rehabilitation; OQLQ = Osteoporosis Quality of Life Questionnaire; SPPB = Short Physical Performance Battery; VAS = visual analogue scale.

cFaster of two 4-meter walk trials.

d17 (12%) participants failed/did not complete the five times sit-to-stand test (tried but unable – n = 9; could not stand unassisted – n=2; felt unsafe – n = 3; other – n=3).

e13 (9%) participants had to repeat the timed up and go test.

fTimed loaded standing data were collected in 34 participants. Three participants were excluded because they did not complete the TLS at baseline or follow-up because of high blood pressure (n=1), previous shoulder issues (n=1), and reason not reported (n=1). One participant did not complete the baseline assessment.

gEQ5D VAS and VAS pain data were missing in 1 participant.

hShort-form FES-I data were missing in 2 participants.

**Table 3.** Change in Functional Performance and Posture Outcomes After 12 Monthsa Between Exercise Group (N = 71)b and Control Group (N = 70)b

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Variablec** | **Exercise Group** | | **Control** | | **Difference Within Groups** | | **Difference Between Groups** |
| **Baseline**  **Mean (SD)** | **12 Months**  **Mean (SD)** | **Baseline**  **Mean (SD)** | **12 Months**  **Mean (SD)** | **Exercise Group**  **Mean Δ (SD)** | **Control Group**  **Mean Δ (SD)** | **Exercise-Control**  **MD (95% CI)** |
| SPPB | | | | | | | |
| SPPB total score | 9.6 ± 2.2 | 9.7 ± 2.5 | 8.8 ± 2.3 | 9.0 ± 2.3 | 0.10 (2.18) | 0.15 (1.75) | -0.05 (-0.75, 0.65) |
| 4-meter walk test (sec) | 4.1 ± 1.2 | 3.9 ± 1.2 | 4.4 ± 1.2 | 4.4 ± 1.3 | -0.21 (1.15) | -0.06 (0.86) | -0.15 (-0.51, 0.21) |
| 5T-STS test (sec)d | 14.7 ± 6.7 | 12.9 ± 4.4 | 14.9 ± 4.4 | 14.6 ± 4.5 | -1.78 (4.89) | -0.29 (3.58) | -1.49 (-3.13, 0.16) |
| Timed stance tests (points) | 3.6 ± 0.9 | 3.5 ± 0.9 | 3.2 ± 1.2 | 3.1 ± 1.1 | -0.05 (1.11) | -0.10 (1.11) | 0.05 (-0.35, 0.44) |
| BOOMER | | | | | | | |
| BOOMER total score | 13.5 ± 2.2 | 13.6 ± 2.6 | 13.2 ± 2.0 | 13.2 ± 2.3 | 0.16 (1.88) | 0.05 (1.90) | 0.11 (-0.56, 0.78) |
| Functional reach test (cm) | 25.9 ± 7.9 | 26.1 ± 8.2 | 25.8 ± 7.2 | 23.9 ± 7.7 | 0.11 (6.9) | -1.91 (7.00) | 2.02 (-0.45, 4.49) |
| Step test – average no. steps | 12.3 ± 4.2 | 13.6 ± 5.1 | 11.8 ± 4.0 | 12.5 ± 4.3 | 1.36 (2.88) | 0.69 (2.97) | 0.67 (-0.37, 1.70) |
| TUG test (sec) | 11.5 ± 3.7 | 10.6 ± 4.1 | 12.0 ± 3.5 | 11.5 ± 3.5 | -0.88 (2.11) | -0.47 (2.43) | -0.41 (-1.21, 0.40) |
| Timed stance, eyes closed test (sec) | 87.2 ± 15.0 | 83.3 ± 19.4 | 85.4 ± 16.1 | 85.6 ± 17.3 | -3.90 (22.03) | 0.15 (23.21) | -4.05 (-12.1, 3.96) |
| Trunk muscle endurance | | | | | | | |
| TLS test (sec)e | 89.5 ± 37.5 | 95.9 ± 39.9 | 86.7 ± 36.8 | 93.0 ± 35.2 | 6.34 (37.32) | 6.26 (39.08) | 0.08 (-31.53, 31.69) |
| Posture | | | | | | | |
| Occiput-to-wall distance (cm) | 5.3 ± 4.0 | 5.3 ± 4.4 | 6.2 ± 4.7 | 6.1 ± 3.9 | -0.01 (2.44) | -0.15 (2.84) | 0.14 (-0.80, 1.09) |
| Standing height (cm) | 156.5 ± 6.4 | 156.4 ± 6.6 | 156.1 ± 7.2 | 155.9 ± 7.2 | -0.10 (1.16) | -0.25 (1.09) | 0.15 (-0.25, 0.55) |

aData expressed as mean (standard deviation, SD) for within-group change and mean difference (MD) (95% confidence intervals, 95% CI) for between-group differences.

bWithdrawals – exercise group (n = 5) and control group (n = 6) while 3 and 2 additional participants did not complete the functional performance tests at follow-up in the exercise and control group, respectively, due to health reasons.

c5T-STS = five times sit-to-stand; BOOMER = balance outcome measurement in elder rehabilitation; SPPB = short physical performance battery; TLS = timed loaded standing test; TUG = timed up and go.

d17 participants per group did not complete the 5T-STS test.

eLongitudinal timed loaded standing data were collected in 31 participants (17 intervention, 14 control participants) and 5 participants (1 intervention, 4 control participants) did not complete one of the baseline or follow-up assessments.

**Table 4.** Change in Health-Related Quality of Life, Pain, and Behavioural Outcomes After 6 and 12 Monthsa Between Exercise Group (n = 71)b and Control Group (n = 70)b

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Variablec** | **Exercise Group**  **Mean Δ (SD)**  **After 6 Monthsc** | **Control Group**  **Mean Δ (SD)**  **After 6 Monthsc** | **Exercise-Control**  **MD (95% CI)**  **After 6 Monthsc** | **Exercise Group**  **Mean Δ (SD)**  **After 12 Monthsd** | **Control Group**  **Mean Δ (SD)**  **After 12 Monthsd** | **Exercise-Control**  **MD (95% CI)**  **After 12 Monthsd** |
| Quality of Life | | | | | | |
| EQ5D VAS | 1.60 (17.59) | -3.48 (16.61) | 5.08 (-1.04, 11.18) | 0.52 (19.10) | -1.27 (17.70) | 1.79 (-4.66, 8.22) |
| EQ5D HUI score | 0.01 (0.16) | -0.04 (0.16) | 0.05 (-0.01, 0.11) | -0.01 (0.16) | -0.01 (0.12) | 0.00 (-0.04, 0.06) |
| Mini-OQLQ symptoms | 0.25 (1.24) | 0.20 (1.10) | 0.05 (-0.37, 0.47) | 0.33 (1.18) | 0.13 (1.28) | 0.21 (-0.22, 0.64) |
| Mini-OQLQ physical function | 0.07 (1.36) | 0.35 (1.04) | -0.28 (-0.74, 0.18) | 0.24 (1.41) | 0.16 (1.25) | 0.08 (-0.40, 0.57) |
| Mini-OQLQ ADL | 0.14 (1.30) | 0.11 (1.30) | 0.03 (-0.47, 0.52) | 0.23 (1.31) | 0.00 (1.38) | 0.23 (-0.28, 0.73) |
| Mini-OQLQ emotional function | 0.22 (1.55) | 0.21 (1.27) | 0.01 (-0.49, 0.52) | 0.34 (1.53) | -0.07 (1.13) | 0.41 (-0.06, 0.88) |
| Mini-OQLQ leisure | 0.54 (1.54) | 0.24 (1.40) | 0.30 (-0.26, 0.86) | 0.31 (1.21) | 0.41 (1.60) | -0.10 (-0.62, 0.43) |
| VAS Pain | | | | | | |
| Pain at rest | -0.29 (2.82) | -0.29 (2.35) | 0.00 (-0.93, 0.92) | -0.65 (2.55) | -0.34 (2.39) | -0.31 (-1.16, 0.56) |
| Pain during movement | -0.64 (2.86) | -0.57 (2.79) | -0.07 (-1.07, 0.94) | 0.00 (2.12) | -0.23 (2.50) | 0.23 (-0.57, 1.04) |
| Fear of Falling | | | | | | |
| Short-form FES-I | -0.82 (3.32) | -0.97 (4.30) | 0.15 (-1.22, 1.53) | -0.88 (3.34) | -0.44 (3.79) | -0.44 (-1.70, 0.82) |
| Exercise Self-Efficacy | | | | | | |
| Action planning | 0.49 (1.87) | 0.01 (1.46) | 0.48 (-0.15, 1.11) | 0.19 (1.83) | 0.01 (1.55) | 0.18 (-0.42, 0.79) |
| Coping planning | 0.62 (1.89) | -0.18 (2.00) | 0.80 (0.08, 1.53) | 0.12 (1.70) | -0.37 (1.44) | 0.49 (-0.08, 1.05) |
| Intention planning | 0.93 (1.70) | 0.33 (1.92) | 0.60 (-0.07, 1.28) | 0.44 (1.86) | 0.03 (1.72) | 0.41 (-0.23, 1.05) |
| Exercise self-efficacy | -0.28 (0.86) | -0.39 (0.88) | 0.11 (-0.21, 0.43) | -0.47 (0.93) | -0.46 (0.81) | -0.01 (-0.32, 0.31) |

aData expressed as mean (standard deviation, SD) for within-group change and mean difference (MD) (95% confidence intervals, 95% CI) for between-group differences.

bADL = activities of daily living; EQ5D = EuroQOL 5-dimensions questionnaire; FES-I = Falls self-Efficacy Scale International; HUI = health utilities index; OQLQ = Osteoporosis Quality of Life Questionnaire; VAS = visual analogue scale.

cWithdrawals at 6 months – intervention group (n = 4) and control group (n = 5).

dWithdrawals at 12 months – intervention group (n = 5) and control group (n = 6).

**Figure Captions**

**Figure 1.** CONSORT study flow diagram.

**Figure 2.** Mean change in functional performance outcomes – five times sit-to-stand (5T-STS) test time (seconds), timed up and go (TUG) test time (seconds), functional reach test distance (cm), and step test (average number of steps) after 12 months in the exercise and control groups. A between-group difference for change in 5T-STS test time was observed in favor of exercise compared to control (MD: -1.58, 95% CI: -3.09, -0.07, ITT; MD: -1.48, 95% CI: -3.13, 0.16, per-protocol) (**2A**). No statistically significant between-group differences were found for TUG (**2B**), functional reach (**2C**) and step tests (**2D**). All data are expressed as mean change (standard error mean).