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ORIGINAL ARTICLE

Effects of an 18-month community-based, multifaceted, exercise program on patient-reported outcomes in older adults at risk of fracture: secondary analysis of a randomised controlled trial

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Abstract

Summary This study identified that an 18-month community-based, multifaceted, exercise program consisting of resistance, weight-bearing impact, and balance/mobility training combined with osteoporosis education and behavioural support can improve health-related quality of life (HRQoL) and osteoporosis knowledge in older adults at risk of fracture, but only for those adherent to the exercise regime.

Purpose To evaluate the effects of an 18-month community-based exercise, osteoporosis education and behaviour change program (*Osteo-cise: Strong Bones for Life*) on HRQoL, osteoporosis knowledge and osteoporosis health beliefs.

Methods This was a secondary analysis of an 18-month randomised controlled trial in which 162 older adults aged $\geq$ 60 years with osteopenia or increased falls/fracture risk were randomized to the *Osteo-cise* program ($n = 81$) or control group ($n = 81$). The program consisted of progressive resistance, weight-bearing impact and balance training (3 days/week); osteoporosis education to facilitate self-management of musculoskeletal health and behavioural support to enhance adherence to exercise. HRQoL, osteoporosis knowledge and osteoporosis health beliefs were assessed using the EuroQoL questionnaire (EQ-5D-3L), Osteoporosis Knowledge Assessment Tool and Osteoporosis Health Belief Scale, respectively.

Results Overall, 148 participants (91%) completed the trial. Mean exercise adherence was 55% and mean attendance for the three osteoporosis educational sessions ranged from 63-82%. After 12 and 18 months, there were no significant effects of the *Osteo-cise* program on HRQoL, osteoporosis knowledge or health beliefs relative to controls. Per protocol analyses ($\geq$ 66% exercise adherence; $n = 41$) revealed a significant net benefit in EQ-5D-3L utility for the *Osteo-cise* group relative to controls after 12 months ($P = 0.024$) and 18 months ($P = 0.029$) and a significant net improvement in osteoporosis knowledge scores at 18 months ($P = 0.014$).

Conclusion This study supports the importance of adherence to exercise regimes, as adherence to the *Osteo-cise: Strong Bones for Life* program was associated with improvements in HRQoL and osteoporosis knowledge in older adults at increased risk for falls and fractures.

Trial registration number: ACTRN12609000100291.

Keywords Education · Exercise · Falls · Osteoporosis · Patient-reported outcomes · Quality of life

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Introduction

Fragility fractures are associated with both personal and healthcare system burdens including limitations in physical functioning, reduced health-related quality of life (HRQoL), increased risk of mortality and greater healthcare utilisation [1–5]. It is well established that bone loss leading to osteopenia or osteoporosis results in increased risk of fractures. Prescription of pharmacological agents is commonly used as first-line treatment to prevent fragility fractures in those with osteoporosis or a history of a low-trauma fracture. These medications have been shown to reduce fracture risk by 30–70%, depending on the skeletal site, treatment modality, and adherence to the medication regime [6, 7]. However, these treatments have no effect on falls risk, a key risk factor contributing to fragility fractures [8]. Exercise is the only strategy that can maintain or improve bone health while simultaneously improving multiple modifiable risk factors for fractures such as bone and muscle strength, dynamic balance and functional performance [9].

Clinical guidelines for osteoporosis and fracture prevention recommend exercise as a management strategy for optimising bone health to prevent fractures among older people [10–12], but it must be appropriately prescribed, and adherence needs to be maintained. Specifically, it should include moderate- to high-intensity progressive resistance training with weight-bearing impact exercises and challenging balance training along with strategies to promote adherence (e.g. use of behaviour change techniques, promoting social interaction). In an 18-month randomised controlled trial in community-dwelling men and women aged 60 years and over with osteopenia or at increased falls/fracture risk [13], we previously reported that a multifaceted intervention (termed *Osteo-cise: Strong Bones for Life*) consisting of a multi-component resistance, weight-bearing impact and balance/mobility training program (3-days/week) combined with osteoporosis education and behavioural support was safe and effective for improving lumbar spine and femoral neck areal bone mineral density (BMD), muscle strength and multiple physical function outcomes [14, 15]. While these findings support the clinical effectiveness of the intervention, clinical measures provide only a partial picture of health status. Patient-reported outcomes (PROs) are measurements that come directly from individuals themselves, without interpretation of the response by a clinician or another person, and are increasingly being evaluated in clinical trials [16]. Measurement of PROs has been highlighted as an important step toward improving the appropriateness, effectiveness and delivery of patient-centred care [17, 18]. Therefore, information on a number of pre-specified PROs was collected in this study including HRQoL, osteoporosis knowledge, and osteoporosis attitudes and beliefs.

The measurement of HRQoL can provide valuable information on a patient's health status across multiple domains of health including physical, mental and social health, and provide information relating to the effects of an illness or treatment [19]. Improved HRQoL is also associated with decreased risk of long-term mortality in older adults [20], as well as in older adults post-fracture [21]. Furthermore, adherence to osteoporosis medications in older patients is often poor [22], with lack of patient understanding and inability to self-manage health being common contributing factors [23]. Multifaceted osteoporosis education focusing on disease-specific knowledge and self-management strategies (e.g. medication, diet and exercise) can have a positive impact on a patient's ability to engage in preventive behaviours and adhere to osteoporosis treatment [24], even more so when combined with behavioural counselling [25]. Therefore, the aim of this study was to evaluate the effect of the *Osteo-cise: Strong Bones for Life* program on the PROs including HRQoL, osteoporosis knowledge and osteoporosis attitudes and beliefs.

Materials and methods

Study design

A detailed description of the study methodology has been described elsewhere [13–15]; therefore, a brief overview is provided below. This study was an 18-month randomised controlled trial in which participants were randomly allocated (stratified by sex) to either the community-based *Osteo-cise: Strong Bones for Life* program (hereafter referred to as '*Osteo-cise*') or a standard care control group. The study was divided into two phases: a 12-month 'supervised and structured' phase where the research team closely monitored the implementation of the program and a 6-month 'research-to-practice' phase where each fitness centre was asked to undertake the program independently. All participants were also prescribed 1000 IU of vitamin D and 700 mg of calcium supplements daily throughout the 18 months.

Participants

Adults living in the Western and surrounding suburbs of Melbourne, Australia, who enquired about participating in the study were first screened via telephone for the following inclusion criteria: aged ≥ 60 years, body mass index (BMI) < 40 kg/m^2, no diagnosis of osteoporosis or fragility fracture in the previous 6 months, had not undertaken any resistance training or weight-bearing impact exercises (more than once a week) over the previous 3 months, and confirmed they had the ability to travel to a local fitness centre three times a week for 18 months to complete the exercise program. Individuals were excluded if they were current smokers, had a medical condition (e.g. type 1 diabetes) or were taking medications (e.g. bisphosphonates) known to influence bone resorption or fracture/falls risk, had commenced taking vitamin D or calcium supplements in the preceding 6 months or, for women only, had taken hormone replacement therapy in the previous 6 months. Those who met the initial screening criteria were invited to have a dual-energy X-ray absorptiometry (DXA) of the hip and spine. Individuals who had osteopenia (T-score between − 1.0 and − 2.5 SD) or a normal BMD (T-score greater than − 1.0 SD) but were classified as being at increased fracture risk based on a falls/fracture risk questionnaire [26] were eligible for inclusion. Patients with osteoporosis (T-score ≤ − 2.5 SD) were excluded and advised to consult their primary care physician for follow-up care. In the final step of the screening process, participants required approval from their primary care physician to confirm that they were clear of any contraindicated medical conditions to complete the exercise program.

Intervention

The community-based *Osteo-cise* program comprised four distinct components. The first component (Osteo-*cise*) was an individually tailored multi-modal exercise program, within one of seven community-based fitness centres across Western Melbourne, which included traditional and high-velocity progressive resistance training, moderate-intensity weight-bearing impact exercises and high-challenge balance and mobility exercises (~ 60-min session). The initial 12-month program was divided into a 4-week “adoption phase” followed by four increasingly challenging 12-week mesocycles. During the final 6-month “research-to-practice” phase, each leisure centre assumed responsibility for delivering the program. All sessions were supervised by certified exercise trainers and participants were instructed to complete the exercise program 3 days a week (non-consecutive). A more detailed account of the training methods and exercise progressions is reported in our protocol paper [13]. Briefly, the progressive resistance training protocol included a mixture of machine and free weight exercises, and training intensity was monitored using the modified BORG (1–10) Rating of Perceived Exertion (RPE) scale. In the “adoption” training phase, participants performed two sets of 12–15 repetitions at 40–60% of one-repetition maximum (RPE 3–4; “moderate to somewhat hard”). Thereafter, participants were prescribed two sets of 10–15 repetitions (RPE 3–4) for the first 4 weeks of each mesocycle, followed by 8–12 repetitions (RPE 5–8; “hard to very hard”) for each exercise for the remaining 8 weeks of each mesocycle. Two to three weight-bearing impact exercises were undertaken each session (3 sets; 10–20 repetitions) and included stationary movements (e.g. stomping), forward and backward movements (e.g. box step-ups) and lateral/multidirectional movements (e.g. side-to-side shuffle). The intensity of these exercises was progressively increased by increasing jump height or the rate of impact loading, by adding additional weight or by incorporating multidirectional movement patterns to diversify the load distribution. Two high-challenge balance and mobility exercises were performed in each session (e.g. fit-ball exercises, standing balance and dynamic functional exercises) and were either maintained for up to 30 s or performed for a given number of repetitions. The second component (Osteo-*Adopt*) involved the incorporation of behavioural change strategies to encourage uptake and long-term adherence to exercise participation. This included strategies guided by the Transtheoretical Stages of Change Model and Social Cognitive Theory such as organising participants into small exercise groups to promote social interaction, positive reinforcement though telephone calls from the research staff or exercise trainers and self-monitoring of progression through the completion of exercise cards and the establishment of short- and long-term exercise goals to help recognise motivating factors to attaining these goals. The third component (Osteo-*Ed*) was a series of osteoporosis education seminars that were intended to provide participants with the skills required to manage their own musculoskeletal health. Three education seminars were undertaken by research staff (~ 60-min each) at selected community leisure centres on the following topics: (1) risk factors for osteoporosis, (2) the importance of exercise for optimal bone and muscle health and (3) nutritional strategies for bone and muscle health. The education sessions were designed to be an informal gathering where participants were encouraged to ask questions and have open discussions. The final component (Osteo-*Instruct*) was a full-day workshop that exercise trainers administering the *Osteo-cise* program were required to attend. This workshop educated trainers on the objectives and structure of the *Osteo-cise* program to ensure that it was implemented as intended. The workshop also presented information on the latest research in osteoporosis treatment and management, strategies for falls and fracture prevention and information on exercise and nutrition for bone health. All trainers were provided with a training manual that they could refer back to throughout the study.

Usual care (self-management) control group

Control group participants were provided with educational material from Osteoporosis Australia (now regarded as Healthy Bones Australia) about the risk factors and management of osteoporosis and fractures. This information was freely available to all consumers though the Osteoporosis Australia website.

Study outcomes

Demographic, health and medical history

Information of demographic, health and medical history was collected via questionnaire at the baseline visit. Height (to the nearest 0.1 cm) and weight (to the nearest 0.1 kg) were measured using standard procedures, from which BMI was calculated.

Health-related quality of life

Changes in HRQoL were assessed using the validated EuroQoL questionnaire (EQ-5D-3L) [27] at baseline, 6, 12 and 18 months. The EQ-5D-3L is a descriptive tool that measures five dimensions of health (mobility, self-care, activities of daily living, pain and discomfort, anxiety and depression) at three levels of severity (no problems, some problems, major problems). From these responses, an EQ-5D utility score can be calculated that ranges from − 1 (indicating a state worse than death) to 1 (full health). We used the Australian time utility weights from the general Australian population samples to calculate utility scores [28]. The EQ-5D-3L also includes a visual analogue scale (VAS) that measures health status, which requires participants to rate their health state on a scale from 0 (worst conceivable health state) to 100 (best conceivable health state).

Osteoporosis knowledge

Knowledge of osteoporosis was measured using the Osteoporosis Knowledge Assessment Tool (OKAT) [29] at baseline, 12 and 18 months. The OKAT is a validated questionnaire that includes 20 questions regarding four basic knowledge areas about osteoporosis: possible risk factors, preventative strategies, identification of the disease and treatment availability. Each question can be answered with 'true', 'false' or 'do not know', with the final score based on the number of correctly answered items [29].

Osteoporosis attitudes and beliefs

The Osteoporosis Health Belief Scale (OHBS) [30] was used to measure attitudes and health beliefs related to osteoporosis at baseline, 12 and 18 months. The OHBS is a validated 42-item self-report questionnaire designed to assess perceived health awareness of osteoporosis across seven subscales (susceptibility, seriousness, benefits of exercise, benefits of calcium intake, barriers to exercise, barriers to calcium intake, health motivation). Each subscale consists of six items on a 5-point Likert scale ranging from one (strongly disagree) to five (strongly agree); thus, the total possible score ranges from 42 to 210. Higher scores indicate healthy beliefs, except for the two barrier subscales, where higher scores indicate negative health beliefs [30].

Intervention adherence

To determine adherence to the *Osteo-cise* program, participants completed exercise cards for each of their training sessions. These were reviewed regularly by the trainers to ensure accuracy and completeness and then returned to the research team. Attendance at the osteoporosis education seminars was recorded by a research staff member.

Statistical analyses

The number of participants required for this study was based on the expected difference between groups for the primary outcome measures of femoral neck BMD and functional muscle power [13]. As recommended by guidelines [31], no post hoc power calculations were performed for the analysis of secondary outcomes in this study. Descriptive statistics were calculated for demographic variables and summarized as mean ± SD or frequency (percentage). All results were initially analysed using intention-to-treat (ITT), where data from all participants were included in the analyses regardless of adherence to the intervention. No data imputation was undertaken. All data were checked for normality and homogeneity of variance by visual inspection of the residuals. General linear mixed models with random effects were used to assess time (within-group) and group-by-time interactions, adjusting for age and sex (model 1) and baseline scores (model 2). Per protocol analyses were also conducted with the 41 *Osteo-cise* participants with at least 66% adherence to the exercise program (equivalent to two sessions per week over the entire 18 months). All data were presented as unadjusted mean ± SD or mean change and 95% confidence intervals (CI), unless stated otherwise. Statistical significance level was set at $p < 0.05$. All analyses were performed using STATA software (version 17, Stata Corporation Inc., College Station, TX, USA).

Results

Participants

Of the 696 individuals assessed for eligibility, 162 participants were randomly allocated to the *Osteo-cise* ($n = 81$) or control ($n = 81$) groups. The majority of participants were female

($n = 119$; 73.5%) and the mean age was 67.4 years (range 59 - 86 years). Most participants were retired or not working at the time of the study ($n = 122$; 76.7%), mean BMI was 27.4 (44.4% were overweight and 25.9% were obese), and over half the participants reported multimorbidity. A total of 14 participants did not complete the 18-month follow-up (4 *Osteo-cise* and 10 controls), leaving 148 participants (91%) for the final analyses. Detailed information on baseline characteristics of participants and study attrition has been reported elsewhere [14].

Intervention adherence

Mean adherence to the exercise program after 12 and 18 months was 59% and 55%, respectively. On average, 24% of the intervention group attended < 1 session per week, 20% attended between 1.0 and 1.9 sessions per week, and 56% attended ≥ 2 sessions per week. Overall, 32% of intervention participants did not complete any exercise sessions during the "research-to-practice" transition. For calcium and vitamin D supplementation, mean adherence did not differ between groups during the trial [calcium: 87% (*Osteo-cise*) vs. 88% (controls); vitamin D: 93% (*Osteo-cise*) vs. 93% (controls)]. For the three *Osteo-Ed* sessions, mean attendance by participants was 82% for session 1, 63% for session 2 and 65% for session 3.

Study outcomes

Health-related quality of life

There were no statistically significant within-group changes or between-group differences in EQ-5D utility and EQ-5D VAS at any follow-up timepoints (Table 1). All results remained unchanged after adjusting for age, sex and baseline values. In the per protocol analyses (Supplementary Table S1), there was a significant improvement in EQ-5D utility score in the *Osteo-cise* group relative to controls after 12 months (net difference, 0.05; $P = 0.024$) and 18 months (net difference, 0.04; $P = 0.029$) when adjusting for baseline values. EQ-5D VAS significantly improved in the *Osteo-cise* group after 6 months (mean change, 4.29; 95% CI: 0.06–8.52), but there were no differences relative to controls at any time.

Osteoporosis knowledge

Osteoporosis knowledge scores were low at baseline in both groups (7.68 ± 2.66 vs. 6.61 ± 3.44 for *Osteo-cise* and control groups, respectively). After 12 and 18 months, both groups showed similar significant improvements in OKAT scores relative to baseline. When adjusting for baseline values, there was a trend for a greater net benefit in the *Osteo-cise* group compared with controls at 18 months ($P = 0.062$). Similar results were observed in the per protocol analysis (Supplementary Table S2) with the exception that after adjusting for baseline values, there was a significant net improvement in OKAT score at 18 months in the *Osteo-cise* group compared with the control group ($P = 0.014$).

Osteoporosis attitudes and beliefs

For total OHBS scores, there were no within-group changes or between-group differences after 12 or

Table 1 Mean baseline scores, mean within-group changes and net between-group differences between the *Osteo-cise* and control groups for health-related quality of life (HRQoL) after 6, 12 and 18 months

	Study group			Group x time effects (*P*-value)		
	Osteo-cise ($n = 74$)	Control ($n = 69$)	Net difference (95% CI)	Unadjusted	Model 1[a]	Model 2[b]
EQ-5D utility						
Baseline	0.84 ± 0.16	0.86 ± 0.13	–	–	–	–
Δ6 months	-0.02 (-0.05, 0.02)	0.00 (− 0.04, 0.03)	− 0.02 (− 0.07, 0.04)	0.975	0.978	0.541
Δ12 months	0.00 (-0.04, 0.04)	0.00 (-0.04, 0.04)	0.00 (-0.05, 0.06)	0.806	0.803	0.894
Δ18 months	0.02 (-0.01, 0.06)	0.01 (-0.03, 0.05)	0.01 (-0.03, 0.07)	0.343	0.341	0.473
EQ-5D VAS						
Baseline	80.70 ± 12.83	83.06 ± 13.27	–	–	–	–
Δ6 months	1.08 (− 2.26, 4.42)	0.15 (− 2.55, 2.86)	0.93 (− 3.33, 5.19)	0.603	0.608	0.924
Δ12 months	1.43 (− 1.16, 4.02)	− 0.73 (− 3.86, 2.40)	2.16 (− 1.85, 6.17)	0.174	0.175	0.473
Δ18 months	1.68 (− 1.69, 5.04)	− 1.42 (− 4.06, 1.22)	3.10 (− 1.19, 7.38)	0.128	0.129	0.257

Baseline values represent means ± SD. Within group changes and net differences relative to baseline represent means with 95% CI. All data are unadjusted values

[a]Adjusted for age and sex

[b]Adjusted for baseline values

Table 2 Mean baseline scores, mean within-group changes and net between-group differences between the *Osteo-cise* and control groups for Osteoporosis Knowledge and Osteoporosis Attitudes and Beliefs after 12 and 18 months

	Study group			Group × time effects (*P*-value)		
	Osteo-cise (*n* = 76)	Control (*n* = 72)	Net difference (95% CI)	Unadjusted	Model 1[a]	Model 2[b]
Osteoporosis Knowledge Assessment Tool (OKAT)						
Baseline	7.68 ± 2.66	6.61 ± 3.44	–	–	–	–
Δ12 months	**0.92 (0.27, 1.57)**	**1.05 (0.29, 1.82)**	−0.13 (−1.13, 0.86)	0.667	0.648	0.386
Δ18 months	**1.28 (0.57, 1.98)**	**0.93 (0.26, 1.61)**	0.35 (−0.62, 1.31)	0.558	0.585	0.062
Osteoporosis Health Belief Scale (OHBS)						
Susceptibility						
Baseline	20.04 ± 4.93	19.91 ± 4.61	–	–	–	–
Δ12 months	**1.07 (0.04, 2.10)**	**1.01 (0.08, 1.95)**	0.06 (−1.33, 1.43)	0.969	0.967	0.977
Δ18 months	0.54 (-0.44, 1.52)	**1.28 (0.41, 2.14)**	−0.74 (−2.04, 0.56)	0.240	0.246	0.187
Seriousness						
Baseline	18.34 ± 3.86	19.39 ± 4.68	–	–	–	–
Δ12 months	0.23 (−0.72, 1.17)	0.51 (−0.27, 1.30)	−0.28 (−1.51, 0.93)	0.599	0.601	0.197
Δ18 months	0.00 (−0.82, 0.82)	0.88 (−0.03, 1.78)	−0.88 (−2.08, 0.33)	0.192	0.196	**0.027**
Benefits of exercise						
Baseline	11.30 ± 3.05	11.19 ± 2.86	–	–	–	–
Δ12 months	−0.39 (−1.22, 0.45)	0.04 (−0.77, 0.85)	−0.43 (−1.58, 0.73)	0.537	0.547	0.538
Δ18 months	0.57 (−0.36, 1.49)	0.63 (−0.15, 1.40)	−0.06 (−1.26, 1.14)	0.894	0.911	0.989
Benefits of calcium intake						
Baseline	14.14 ± 3.55	14.05 ± 3.19	–	–	–	–
Δ12 months	0.01 (−0.75, 0.77)	−0.01 (−0.82, 0.79)	0.02 (−1.07, 1.13)	0.860	0.850	0.762
Δ18 months	−0.04 (−0.93, 0.85)	0.61 (−0.22, 1.44)	−0.65 (−1.86, 0.55)	0.360	0.363	0.436
Barriers to exercise						
Baseline	24.00 ± 3.47	24.33 ± 3.38	–	–	–	–
Δ12 months	0.12 (−0.83, 1.07)	−0.73 (−1.67, 0.21)	0.85 (−0.48, 2.18)	0.228	0.226	0.265
Δ18 months	−0.22 (−1.04, 0.60)	−0.51 (−1.44, 0.41)	0.29 (−0.93, 1.51)	0.647	0.638	0.795
Barriers to calcium intake						
Baseline	23.30 ± 3.65	23.34 ± 4.22	–	–	–	–
Δ12 months	−0.11 (−1.07, 0.86)	0.11 (−1.04, 1.25)	−0.21 (−1.70, 1.27)	0.735	0.727	0.661
Δ18 months	0.05 (−0.61, 0.71)	0.00 (−1.18, 1.18)	0.05 (−1.27, 1.38)	0.974	0.996	0.965
Health motivation						
Baseline	12.32 ± 3.33	11.77 ± 3.26	–	–	–	–
Δ12 months	0.00 (−0.98, 0.98)	0.27 (−0.38, 0.92)	−0.27 (−1.44, 0.90)	0.557	0.567	0.895
Δ18 months	0.01 (−0.77, 0.80)	0.39 (−0.32, 1.10)	−0.38 (−1.43, 0.68)	0.489	0.498	0.899
Total OHBS score						
Baseline	123.44 ± 10.29	123.99 ± 11.14	–	–	–	–
Δ12 months	0.93 (−1.97, 3.84)	1.20 (−1.7,4.14)	−0.27 (−4.37, 3.83)	0.882	0.894	0.717
Δ18 months	0.91 (−1.86, 3.68)	**3.26 (0.46, 6.07)**	−2.35 (−6.27, 1.55)	0.292	0.303	0.181

Baseline values represent means ± SD. Within group changes and net differences relative to baseline represent means with 95% CI. All data are unadjusted values. Bold figures indicate a significant P-value of < 0.05

[a]Adjusted for age and sex

[b]Adjusted for baseline values

18 months in the unadjusted or adjusted models, except for an improvement in controls after 18 months (Table 2). Similarly, most of the OHBS subscales showed no within-group changes or between-group differences, except for perceived seriousness, which showed a significant net benefit in favour of controls ($P = 0.027$) at 18 months after adjusting for baseline values. In the per protocol analysis, similar results were observed (Supplementary Table S2).

Discussion

The main findings from this secondary analysis of an 18-month randomised controlled trial of a community-based, multifaceted osteoporosis prevention program (*Osteo-cise: Strong Bones for Life*) were that there were no significant effects on HRQoL, osteoporosis knowledge or osteoporosis attitudes and beliefs compared with usual care. However, per protocol analyses revealed that those most adherent to exercise training did experience significant improvements in both HRQoL and osteoporosis knowledge compared with usual care. This suggests that older adults who adhere to a multifaceted osteoporosis prevention program consisting of a multi-component resistance, weight-bearing impact and balance/mobility training program combined with osteoporosis education and behavioural support can experience improvements in these key PROs.

The mechanism(s) of how exercise training may improve HRQoL in older adults are not well understood. It has been suggested that the beneficial effect of exercise on HRQoL may be explained by a number of factors including improvements in muscle strength and/or function, improved ability to undertake basic activities of daily living, and increased social interaction and/or release of neurotransmitters (e.g. endorphins) [32–34]. We previously reported that the *Osteo-cise* program was effective for improving lumbar spine and femoral neck areal BMD, muscle strength and multiple physical function outcomes, despite a mean adherence of 55% [14, 15]. However, in this study, we found no significant benefits of the *Osteo-cise* program on HRQoL measured by EQ-5D utility scores, overall health state (EQ-5D VAS), or the five individual domains of the EQ-5D-3L. Previous randomised controlled trials examining the effect of various exercise interventions in community-dwelling older adults targeting musculoskeletal health and/or falls prevention have reported benefits on physical and psychosocial HRQoL domains, but findings were not consistent across all interventions [35–41]. The reasons for these contrasting results most likely relate to differences in exercise modality (type, frequency), exercise duration (ranging from 1-12 months) and population characteristics.

Few studies have evaluated the combined effects of a comparable multifaceted program consisting of exercise, education and behavioural support. In a 12-month randomised controlled trial of 591 community-dwelling older adults determined as ‘high falls risk’, Vaapio et al. reported no significant improvements in 13 of the 15 dimensions of HRQoL after a multifactorial fall prevention program consisting of a geriatric assessment (falls risk factor assessment), twice-weekly group exercise classes (balance, muscle strength and respiratory function), educational lectures on themes related to falls prevention, and psychosocial group activities [37]. A likely contributing factor for these findings was that HRQoL scores of their participants were already high at baseline, thus making it difficult to identify any positive changes. In support of this notion, the mean EQ-5D utility scores of participants in our study at baseline in both groups were higher than those reported in the general population of the same age [42]. This may have reduced our capacity to detect any substantial improvements in HRQoL. However, we did observe that those who adhered to the *Osteo-cise* program (at least 66% adherence to the exercise program over the entire 18 months — equivalent to two sessions per week) experienced a statistically significant benefit in EQ-5D utility, relative to controls. This highlights that the effectiveness of exercise interventions in older adults on HRQoL outcomes may be largely influenced by ongoing participation, further reinforcing the importance of older adults adhering to exercise regimes. Non-adherence to structured exercise programs is influenced by a number of factors in the older population. These include individual factors (low socioeconomic status, chronic illness, poor general health, physical function limitations, lack of motivation, low self-efficacy for physical activity) and program-related factors (method of delivery, duration, location) [43, 44]. Administrators of long-term exercise programs should consider these adherence predictors when evaluating future program needs and enhancements. The use of digital health technologies and interventions appear to be promising concepts to improve exercise adherence for community-dwelling older adults [45]; however, supporting evidence is currently not sufficient to make specific recommendations. It is also imperative that primary care physicians receive education and training regarding the beneficial and operational applications of exercise, with the intention of improving referral rates to allied health professionals such as exercise physiologists [46].

There is evidence that multifactorial exercise interventions which incorporate education and behaviour change techniques can enhance knowledge of osteoporosis, improve initiation and adherence to osteoporosis preventive actions (e.g. uptake and adherence to calcium and vitamin D supplementation), and improve clinical outcomes such as BMD [25, 47, 48]. The *Osteo-cise* program incorporated behaviour change strategies to encourage positive changes in health behaviours and maximise participant adherence to the program, and additionally provided a series of face-to-face education seminars to maximise osteoporosis-related knowledge. Despite this, there were no significant differences between groups in osteoporosis knowledge scores after 12 and 18 months. This may be explained in part by the modest attendance to the final two education seminars (mean 63% and 65%, respectively), and thus, the *Osteo*-cise participants may have missed out on key information about bone and muscle health. Interestingly, both the *Osteo-cise* and usual care control group experienced similar significant improvements in osteoporosis knowledge scores after 12 and 18 months. The improvements in osteoporosis knowledge in the control group may be related to the educational materials they were provided with as part of the trial. Specifically, participants in the control group received educational fact sheets about the risk factors and management of osteoporosis and fractures, which aim to enable older people to actively take charge of their own bone health and seek appropriate services or treatments to help prevent osteoporosis, falls and fragility fractures. Previous research has shown that providing education interventions alone can improve knowledge of bone health in older people, as well as improve the initiation and adherence of osteoporosis-related medication and calcium and vitamin D supplementation [49, 50].

Another key finding from this study was that there were no net benefits in osteoporosis attitudes and beliefs between groups throughout the 18-month intervention. Mean total OHBS score for groups was quite low at baseline and remained low at all follow-up points, indicating that our cohort had generally low attitudes and health beliefs related to osteoporosis. Health beliefs can impact decisions to change preventive health behaviours, which may have influenced participation in our exercise program — only half of the *Osteo-cise* group participants were at least 66% adherent to the exercise program over the trial period. There is also some evidence suggesting that osteoporosis knowledge is correlated with osteoporosis preventive beliefs and behaviours [47], and thus, the lack of any benefits of the *Osteo-cise* program in the ITT analysis on osteoporosis knowledge may also help to explain these findings.

Strengths and limitations

The key strengths and limitations of the *Osteo-cise* intervention trial have been reported previously [14, 15]. Briefly, the strengths of this study were the successful delivery of a 'real-world' multimodal and multifaceted exercise and osteoporosis prevention program in community-based leisure centres, the randomised study design, the long follow-up period, and the high participant retention. When interpreting the results of the present analyses, there are some limitations that should be considered. First, this study may have been underpowered to detect differences in HRQoL and osteoporosis knowledge and heath beliefs as these were secondary outcomes. Second, the moderate adherence to the exercise program and attendance at the *Osteo-cise* education sessions may have likely attenuated the long-term effectiveness of the program on both primary and secondary outcomes. Finally, as with most randomised controlled trials, we used narrow inclusion criteria limiting the generalisability of our findings to the broader population of older people. However, the participants included in this study did reflect the typical profile of the population with or at risk for fragility fractures (e.g. the majority were women; mean age was > 65 years; and the majority had osteopenia).

Conclusions

In this secondary analysis of an 18-month community-based, multifaceted osteoporosis prevention program (*Osteo-cise: Strong Bones for Life*), there were no benefits for PROs in men and women at an increased risk of falls/fractures compared with usual care despite showing improvements in multiple musculoskeletal and functional outcomes. However, we did observe a significant improvement in HRQoL and osteoporosis knowledge in *Osteo-cise* participants most adherent to the exercise program, highlighting the need to identify strategies that promote long-term adherence to such exercise programs in community-dwelling older adults.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00198-023-06693-y.

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Data availability Access to this data should bescussed with the data custodian (RMD).

Code availability Not applicable.

Declarations

Ethics approval Ethics approval was obtained from the Melbourne Health Human Research Ethics Committee (2008.136) and the trial was registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12609000100291).

Informed consent Informed consent was obtained from all individual participants included in the study.

Consent for publication All the authors approved the final manuscript for publication.

Conflicts of interest None.

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