

Menopause Osteoporosis and Bone Intervention Using Lifestyle Exercise: A Randomized Controlled Study

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ABSTRACT

Background: The aim of the study was to examine the feasibility for postmenopausal women of a bone-strengthening jumping intervention, which has been previously successful for premenopausal women. **Materials and Methods:** Forty-nine participants (mean ± standard deviation [SD] age = 57.8 ± 4.3 years) were randomized into either an exercise intervention or sham-control group in a double-blinded fashion. The intervention consisted of 10 maximal, rest-inserted countermovement jumps, performed three times a week on a hard surface without shoes for 8 months. Sham-control participants performed unilateral balance exercises of equivalent duration. **Results:** The jumps were well tolerated, with women in the jumping group completing 95% of the prescribed exercise. Of the participants who completed the study (*n* = 23 intervention, *n* = 16 control), there were no significant differences in broadband ultrasound attenuation (BUA) using quantitative ultrasound (QUS) of the calcaneum within and between groups (mean ± SD BUA = 64.9 ± 7.3 and 66.6 ± 6.5 dB/MHz for intervention pre- and post-trial, respectively, versus mean ± SD BUA = 63.6 ± 4.2 and 64.4 ± 4.5 dB/MHz for sham-controls pre- and post-trial, respectively) or for any QUS parameters, although there was a 3% increase in BUA for intervention participants. **Conclusions:** Recruitment and participation rates were feasible for this duration of study and the exercise was acceptable. For a future study of this nature, 48 participants would be required to ensure adequate power, especially as lifestyle variations and post-menopausal hypoestrogenism prevent substantial gains in bone strength with high-impact exercise.

KEYWORDS: *Exercise training, jumping, postmenopausal*

INTRODUCTION

The prevalence of osteoporosis, and associated fracture, increases substantially when women enter menopause, owing to a hypoestrogenic-related increase in bone resorption.^[1] Strategies for increasing or maintaining bone health for postmenopausal women are, therefore, required to reduce menopause-related osteoporotic fracture.

Weight-bearing exercise, due to the mechanical loading on the bone, is a nonpharmacological strategy for improving bone strength and reducing the risk of osteoporosis. Dynamic, high-impact exercise, especially jumping, has been found to significantly improve bone strength among premenopausal women.^[2-7]

Countermovement jumps provide a suitable osteogenic stimulus since ground-reaction forces (GRF) have been reported as being 5.6 times body mass.^[8] Jumping might, therefore, be a suitable, time-efficient means of maintaining or improving bone strength.

Among postmenopausal women, in contrast to premenopausal populations, there are mixed findings regarding the effectiveness of jumping programs for improving bone mass. For instance, Bassey *et al.*^[9] found

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no effect on bone mineral density (BMD) of a 12-month jumping program among postmenopausal women, irrespective of hormone replacement therapy (HRT) use, whereas just 5 months of the same program among premenopausal women significantly increased femoral neck BMD relative to controls.^[9] Similarly, other jumping interventions have resulted in nonsignificant findings.^[10-12] In contrast, a rope-jumping intervention was found to significantly increase lumbar spine and femoral neck BMD and significantly increase serum osteocalcin levels for postmenopausal women with osteopenia,^[13,14] and femoral neck BMD was improved after a 6-month hopping intervention.^[15] Possible reasons for a lack of effect in some interventions include short study duration,^[12] differences in loading protocol and impact,^[16] and lack of control over extraneous variables (which hopping interventions naturally limit). There have also been variations regarding the postmenopausal hypoestrogen status of participants, in terms of HRT use,^[10-12,15] which may interfere with bone turnover.^[17] In addition, bone sites most proximal to the loading may be more sensitive in detecting change;^[7,18,19] hence, quantitative ultrasound (QUS) of the calcaneus may offer a greater site-specific response.

There may be concerns over how tolerated a jumping program is within a postmenopausal population, with high dropout and low adherence rates being previously reported.^[10,11,18] In a combined aerobic exercise and jumping program, the benefit for hip BMD was felt to be only small because the intensity of the program components was below the intended level, due to participants having comorbidities, not progressing, and due to adherence issues.^[20]

The purpose of the study was to examine the feasibility for a larger study of an 8-month jumping intervention among postmenopausal women, in terms of recruitment, adherence, and acceptability. A further aim was to examine whether broadband ultrasound attenuation (BUA) and speed of sound (SOS) using calcaneal QUS were significantly higher than those obtained preintervention and compared to QUS and SOS of control group participants undertaking sham exercises for an equivalent duration, with the aim also to use data from BUA to estimate sample size for a full-scale trial.

MATERIALS AND METHODS

The study was approved by the institutional research ethics committee (on October 25, 2019; data anonymized to add) before the experiment was started and has been conducted in accordance with the principles set forth in the Helsinki Declaration.

The study design was a feasibility randomized controlled trial, investigating between- and within-group

differences (clinical trial registration number to add [anonymized]). There were two trial arms: an intervention jumping group and a sham-control group.

Participants were recruited from the surrounding community through e-mail, social media, and by face-to-face visits to postmenopausal social groups. Inclusion criteria were female, aged ≥ 50 years, at least 1-year postmenopausal, and not on HRT or hormone-based contraception within 6 months of starting the study. Volunteers were excluded if they were using any medication that may have affected bone turnover; had or had had any bone, metabolic, kidney, liver, thyroid, gastrointestinal, hormonal disorders, or cancer that may have affected bone turnover; had a close family history of osteoporosis; had sustained a fragility fracture in the past 6 months; were a heavy smoker (>20 cigarettes/day); were already undertaking bone-specific jumping or equivalent exercises; had an existing knee, hip, or back injury; or had any medical condition that would prevent them from completing the exercise. Additional exclusions following baseline testing were a body mass index of >35 kg/m², to minimize risk of strain or injury associated with the exercise. These disorders and conditions were determined based initially through verbal interview at the recruitment stage and then confirmed through a self-reported lifestyle/medical history questionnaire at baseline. All participants gave their informed consent.

Following baseline data collection and ascertainment of eligibility, participants were randomized, through computer generation of random numbers, into either the intervention group or sham-control group. Participants were blinded to group allocation. Both groups completed their required program for 8 months, since 200 days is the average duration of remodeling in normal trabecular bone,^[21] and is required for change to be detected.

For the intervention group, participants were required to perform 10 maximal vertical jumps without shoes on a hard surface using an arm swing in countermovement style, with a 10-s rest interval between each jump, on 3 days per week. The jumping program was adapted from a previously established protocol.^[3] Initially, where participants felt unstable, a handheld support was used. Jumps were progressed over time and in accordance with individual needs to include multidirectional movements. Natural progression was deemed to also occur as participants improved their jump height with increased muscular explosiveness.

In the sham-control group, participants were required to perform balance exercises. Balance is an effective treatment for avoiding falls that could potentially lead

to fracture but does not result in a significant change in BMD.^[22] Participants were required to balance on each leg for up to 60 s, which was equivalent in duration to the 10 jumps. The balance exercises, including progressions and starting point, were based on an existing protocol.^[23] The purpose of the sham exercise was to foster the perception of full participation in the study, to decrease dropout, and to blind participants.

To ensure quality control and to improve compliance, video clips of all exercises were provided for the participants, who were encouraged to perform the exercises as demonstrated. Initially, participants were invited to one fully supervised group exercise session per month. These voluntary sessions were used to check that the exercise was being completed correctly, and to ensure progression was appropriate for each participant. Sessions lasted 15–20 min and attendance was monitored through registers. Apart from these supervised exercise sessions, participants were given free choice to determine where and when they did the exercises. To encourage adherence, a group messaging application was used, which enabled thrice-weekly announcements to be posted. All participants were invited to join their respective group application (jumping or balance), which allowed them to share their experiences with other members. All participants were requested to maintain their usual physical activity throughout the study and to complete a daily training log, submitted monthly, which included adverse events. Adherence was calculated using the number of sessions completed out of the total number of sessions that were required.

The primary outcome measures were BUA and SOS as measured by QUS (UBIS 5000 Diagnostic Medical Systems, Montpellier, France). Pretrial, short-term measurement precision with repositioning assessed using intraclass correlation (ICC) was 0.925, $P = 0.001$ (95% confidence interval [CI]: 0.832–0.987). Calibration and quality control was accomplished through an automated verification process just before each examination. The participants' dominant foot was assessed.

Secondary outcome measures included QUS-derived stiffness index (SI), T and Z scores, the timed up-and-go test (TUG), GRF, countermovement jump height, and health-related quality of life (QoL). The TUG is often used in studies on osteoporosis prevention as a measure of fall risk and has an ICC of 0.99.^[24] To estimate the mechanical loading force due to the exercise, GRF was evaluated using a force plate (Advanced Mechanical Technology, Inc., AMTI, Watertown, Massachusetts, US). Data were sampled at 1000 Hz, and peak GRF per body mass (GRF/BM) was determined from take-off and/or landing forces. Countermovement

jump height was also determined from force platform data. Health-related QoL was measured using the SF-36 v2 health survey. A bone-loading history questionnaire bone-specific physical activity (BPAQ),^[25] as well as questions on dietary supplements, caffeine and alcohol consumption, which formed part of the lifestyle/medical screening questionnaire, was used to determine any possible confounders to bone accrual. Outcome measures were taken at study outset (baseline) and at intervention end (8 months).

Differences in baseline characteristics were examined using independent samples t-tests. A repeated measures ANOVA (group \times time) was used for determining significant differences in main and secondary outcome measures. The difference between mean percentage changes in variables was also calculated, with differences assessed using independent samples t-tests. Since only two participants were available for an intention-to-treat analysis, per protocol findings are reported. Partial-eta squared from the ANOVA and correlation data for BUA were used to determine sample size for a full-scale study. Data are described according to mean, standard deviation, 95% CI, and interquartile range (IQR). A $P < 0.05$ was accepted as being statistically significant. Analyses were conducted using SPSS 28.0 (IBM Corp. Released 2021. IBM SPSS Statistics for Windows, Version 28.0. Armonk, NY: IBM Corp).

RESULTS

Forty-nine participants were randomized into the trial arms and 37 analyzed [Figure 1]. Baseline characteristics of the participants who completed the study are given in Table 1. Participants ranged in age from 53 to 66 years.

Participants in the jumping group completed $94.9\% \pm 1.4\%$, IQR = 7.3% of the prescribed exercise and in the sham-control group completed $88.0\% \pm 4.8\%$, IQR = 10.4. There were no adverse events that resulted in the participants stopping the intervention, although there were some minor musculoskeletal issues reported by three participants.

Table 1: Baseline characteristics of analyzed participants for those in the intervention group (jumping exercise) and for those in the sham-control group (balance exercise)

Characteristic	Intervention arm (n=21)	Sham-control arm (n=16)
Age (years)	57.9±4.1	57.8±4.9
Stature (cm)	1.63±0.06	1.62±0.05
Body mass (kg)	67.2±11.9	71.9±15.5
Body mass index (kg/m ²)	25.2±4.4	26.9±6.0
Time since last period (years)	9.7±6.4	9.6±6.7

There were no changes within and between participants for alcohol, caffeine intake, or nicotine use over the trial period. None of the participants were taking calcium supplements at the start of the study, although one participant in the control group started taking supplements mid-way through the intervention. Three participants in the intervention group and two participants in the control group were taking a combined calcium/Vitamin D supplement.

There were no significant differences for any of the baseline participant characteristics, apart from BPAQ results. Mean current BPAQ values were significantly higher (2.13 ± 2.57) for the control group in comparison to those for the intervention group (1.39 ± 0.88) ($t_{21,16} = -1.24, P = 0.032$). Total mean BPAQ results were also significantly higher (45.0 ± 37.8) for the control group in comparison to those for the intervention group (37.3 ± 18.4) ($t = -0.819, P = 0.001$).

There were no significant differences in any of the parameters using QUS of the calcaneus for time or group or for jump height, TUG time, BPAQ, or the QoL physical component summary score [Table 2]. Balance

significantly increased between pre- and post-testing, and QoL mental health component score (MCS) significantly decreased [Table 2]. There was a significant interaction effect for GRF/BM, with mean scores increasing for those in the intervention group [Table 2].

There was a 3.0% increase in BUA compared to only a 1.2% increase in the control group for BUA, a 6.4% increase in SI compared to 2.4% increase in the control group, and only a -17.2 reduction in estimated T score in the intervention group in comparison to a -44.1% reduction in the control group. There was a 9.6% improvement in jump height for the intervention group, resulting in a 31.1% increase in GRF/BM.

Based on partial-eta squared as the effect size measure for the interaction for within and between subjects' BUA and using the correlation data from the present study ($r = 0.787$), a total sample of 48 participants would be required to achieve 80% power for future studies with the same design. Based on the dropout and adherence data from the present study, a total of 56 participants would need to be recruited, 28 in each group. If this number was recruited for a future study,

Table 2: Mean±standard deviation and change of variables pre- and post-trial for intervention (jumping exercise) and sham-control (balance exercise) participants

Measure	Intervention (n=21)		Control (n=16)		P (time)	P (group)	P (group × time)	Δ intervention	Δ control	P*
	Pre	Post	Pre	Post						
BUA (dB/MHz)	64.9±7.3	66.6±6.5	63.6±4.2	64.4±4.5	0.058	0.355	0.441	1.73 (-0.44–3.90)	0.74 (-0.26–1.74)	0.441
SOS (m/s)	1535.2±53.7	1535.8±37.4	1522.1±39.2	1530.0±45.2	0.585	0.461	0.639	0.60 (-21.51–22.71)	7.87 (-15.10–30.85)	0.639
SI (%)	92.0±25.7	94.7±18.5	85.9±15.1	87.6±17.3	0.425	0.284	0.865	2.64 (-6.05–11.33)	1.72 (-4.45–7.90)	0.865
T score	-0.70±1.79	-0.37±1.65	-1.03±1.01	-0.90±1.14	0.179	0.353	0.550	0.33 (-0.24–0.91)	0.13 (-0.13–0.39)	0.548
Z score	0.17±1.71	0.49±1.60	-0.16±1.05	0.07±1.12	0.093	0.411	0.814	0.31 (-0.24–0.86)	0.24 (-0.02–0.86)	0.825
Balance test (s)	14.4±18.1	17.6±21.9	7.0±4.4	22.9±32.5	0.011	0.868	0.082	3.17 (-1.08–7.41)	15.97 (-0.59–32.53)	0.082
TUG (s)	5.60±0.69	5.45±0.59	6.02±1.36	5.90±1.72	0.150	0.236	0.795	-0.16 (-0.40–0.07)	-0.11 (-0.45–0.23)	0.792
GRF/BM (N/kg)	6.67±2.03	8.23±2.10	6.90±3.19	6.61±2.84	0.161	0.333	0.044	1.56 (0.47–2.65)	-0.29 (-1.89–1.31)	0.044
Jump height (cm)	14.4±5.1	15.1±4.2	12.1±7.3	10.8±4.8	0.681	0.056	0.119	0.75 (-0.59–2.10)	-1.28 (-3.83–1.27)	0.119
BPAQ	1.39±0.88	1.59±1.68	2.13±2.57	2.37±2.81	0.621	0.147	0.962	0.20 (-0.70–1.07)	0.24 (-1.55–2.03)	0.962
PCS	55.5±3.4	55.7±4.3	53.1±7.2	53.0±9.2	0.936	0.202	0.839	0.34 (-1.54–1.95)	-0.11 (-2.70–2.48)	0.757
MCS	54.9±3.8	53.6±4.5	52.4±7.7	49.8±8.5	0.038	0.095	0.478	-0.97 (-2.23–0.29)	-2.67 (-6.83–1.49)	0.361

Δ (change) with P* (probability) using an independent samples t-test. P using repeated measures ANOVA for time×group. BUA: Broadband ultrasound attenuation, SOS: Speed of sound, SI: Stiffness index, TUG: Timed-up-and-go test, GRF/BM: Ground reaction force per body mass, BPAQ: Bone-specific physical activity questionnaire, current score, PCS: Physical component summary score, MCS: Mental component summary score from the SF-36v2 health survey

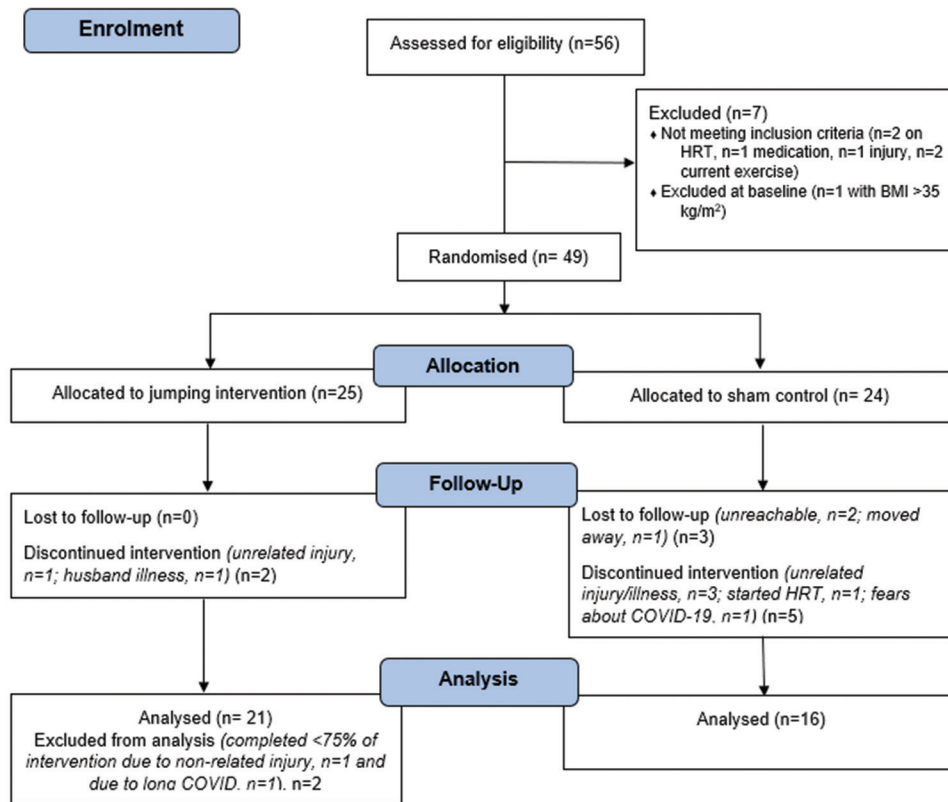


Figure 1: CONSORT flow diagram, showing enrolment, allocation, follow-up and data analysis. Abbreviations: BMI body mass index; HRT hormone replacement therapy

then a participation rate of 87% can be estimated to within a 95% CI of $\pm 9\%$.

DISCUSSION

Recruitment for this 8-month jumping intervention for postmenopausal women proved relatively easy, with a steady flow of volunteers from a local population. Dropout was 8%, and 95% of the prescribed jumping exercise was adhered to. These figures for adherence are higher than those reported in other studies of a similar nature.^[10,12,15] Adherence was possibly helped by the group messaging application, whereby reminders and motivational messages were posted to both groups three times a week. Some of the women liked being part of their group and felt a sense of belonging, knowing that other postmenopausal women were doing the same thing. Exercises were well tolerated and there were no adverse events reported. Since exercise only needed to be completed three times a week, it was rare that participants missed exercise due to a related or nonrelated injury. Participants found the exercise easy to fit into their lifestyle owing to this low-time commitment, which contrasts that of other jumping studies, due to the jumping having been combined with other exercise.^[26,27] The intervention-induced GRFs were a mean of 6.67 times body mass. The increase in GRF

to 8.23 times body mass postintervention may have been because participants had become used to landing with impact, knowing that they could do so without incurring injury. The study was, therefore, deemed feasible, in terms of recruitment, adherence, and tolerance for this population.

There were no significant differences found for any of the bone parameters measured by QUS of the calcaneus between intervention-group and sham-control participants. There was, however, a 3% increase in BUA for the intervention group, suggesting a positive, nonsignificant trend. Based on data from the present study, an initial recruitment of at least 48 participants in total would be needed to achieve sufficient power when using BUA. Where a significant effect on bone strength has been shown due to exercise, sample sizes have been found to be between 33 and 123 participants, compared to only 10–30 participants when no effect has been reported,^[28] which supports the suggestion that a higher sample size is needed.

The lack of significant effect on QUS parameters with jumping, although only preliminary investigated, is consistent with results from other jumping interventions for postmenopausal women^[9-12,17] but disagrees with those of others.^[13-15] The lack of effect may be a result

of the participants' postmenopausal status, since jumping interventions have proved to be effective for premenopausal women,^[2-7,9] and because of the women in the present study not being on HRT. Sugiyama *et al.*^[17] suggested that estrogen may play a role in how bone responds to high-impact exercise through osteoblast activity, as well as how low osteocalcin in premenopausal women may also contribute to increased bone mass. Lack of HRT use may lessen the effect of the high-impact exercise on bone strength, as has been previously proposed.^[20,28]

There were lifestyle changes that occurred due to the study having been carried out during a period of COVID-19-related restrictions. The women changed their habitual physical activity, which could have impacted results; this change was inconsistent between participants. For instance, the BPAQ data give an indication of exercise that increases bone health, and in the control group, there was a trend for an increase in bone physical activity based on this questionnaire. A within-participant control design, as used in the study of Hartley *et al.*,^[15] removes the influence of any change in lifestyle and may be a better research design, to account for unprecedented events.

There were no significant changes in other outcome measures, including jump height and TUG results. In other studies involving jumping, TUG scores were found to improve significantly.^[12,26] The MCS of the QoL questionnaire decreased in the posttesting period compared to the pretesting period in both groups, in contrast to findings from other studies, where an increase in mental health-related QoL was found to occur with jumping.^[12-14,20] This decrease in MCS may be explained by changes to mental health during the COVID-19 lockdown period, which may only be slightly attenuated with exercise.^[29]

There was a rationale for expecting a difference at the calcaneus, owing to its proximity to the impact site, although in two other studies in which QUS was used as an outcome measure for observing the response to high-impact exercise, significant change was not reported,^[16,26] despite there being a significant change in lumbar spine and femoral neck BMD.^[26] The sensitivity of QUS to detect change may therefore be a consideration for future studies. The lack of osteogenic effect in the present study might also be explained by the relatively high bone strength at baseline. If bone is already strong, exercise would not be sufficient to produce new strains.^[30] Three participants in the intervention group had a high BUA (estimated T score of >3.0). For future studies, excluding participants with high initial baseline BUA, and recruiting more

participants or using additional outcome measures to compensate for the low sensitivity of BUA to detect change, are recommended.

CONCLUSIONS

The study proved feasible in terms of recruitment, adherence, acceptability and because there were no exercise-induced adverse events that prevented exercise. Encouragement from regular contact through a group messaging application proved particularly useful for improving adherence. The postmenopausal hypoestrogenism, high baseline BUA for some participants, and lifestyle changes that occurred over this 8-month period may have prevented substantial gains in bone strength with jumping exercise, which were not detected due to the potential lack of sensitivity in the QUS device. More participants will be needed for adequate hypothesis testing.

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Conflicts of interest

There are no conflicts of interest.

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