

Effect of Lifestyle Modification Intervention Programme on Bone Mineral Density among Postmenopausal Women with Osteoporosis

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ABSTRACT: Objectives: Osteoporosis is one of the major public health problems worldwide among postmenopausal osteoporotic women. Lifestyle modification interventions along with pharmacotherapy help to revert bone loss and prevent complications. **Methods:** A randomised controlled trial was conducted at Kasturba Hospital, Manipal from January 2019 to December 2021 among postmenopausal women with osteoporosis. The postmenopausal women who attended the osteoporosis clinic and were within the age group of 45–65 years, could speak and understand English or Kannada and whose bone mineral density (BMD) score was between -1 and -3 were included in the study. The total sample size of the study was 120 with 60 in each of the experimental and control groups. After obtaining informed consent, a stratified block randomisation method was used to allocate the participants to intervention and control groups. The BMD was monitored by the portable ultrasound densitometer by a technician at the outpatient departments. The baseline information was collected by a structured demographic questionnaire. Intervention group participants received a lifestyle modification intervention program (LMIP) whereas the control group received standard regular care from the physician. Follow-up was done at three and six months. **Results:** The results revealed that the increase in the BMD median score among the experimental group was from -2.2 (-2.5– -1.8) to -1.5 (-1.8– -0.65) whereas in the control group, it was from -2.3 (-2.6– -1.9) to -2.0 (-2.4– -1.5). The results of the Mann Whitey U test showed a statistical significance between the intervention and control groups in the post-test after six months (U = 505.5; P < 0.05). Wilcoxon signed rank test showed a significant change in both the intervention and control groups from pre-test to post-test I (3 months) and post-test II (6 months; P < 0.001). **Conclusion:** The lifestyle modification intervention was found to be effective in improving the bone health status of postmenopausal women. Hence it is very important to integrate it into regular therapy.

Keywords: Healthy Lifestyle; Postmenopause; Osteoporosis; Bone Mineral Density; India.

ADVANCES IN KNOWLEDGE

- Effective lifestyle modification intervention was efficient in improving the bone mineral density of postmenopausal women with osteoporosis.
- The constant motivation provided by the researcher to the postmenopausal osteoporotic women helped them to remain committed to the lifestyle modification intervention.
- Counselling and education were also the components of the lifestyle modification intervention programme which were imperative in improving the bone health status of postmenopausal women.

APPLICATIONS TO PATIENT CARE

- Integrating lifestyle modification interventions with pharmacological treatment would aid postmenopausal osteoporotic women in reversing bone loss and accelerating recovery.
- The distribution of informational, educational and communication materials, as well as the provision of organised counselling services to postmenopausal osteoporotic women, would be beneficial for the self-management of osteoporosis.

OSTEOPOROSIS IS A WIDESPREAD ILLNESS that causes a systemic loss of bone mass and microarchitecture, resulting in fragility fractures.¹ Osteoporosis is more commonly seen in older adults and women.² With an increase in the population of older people and an improvement in life expectancy, osteoporosis is becoming a worldwide epidemic. According to estimates, more than 200 million individuals worldwide have osteoporosis and one in three women over 50 and one in five men may experience osteoporotic fractures at some point in

their lifetime.^{3,4} These fractures, which primarily occur at the hip, vertebrae and distal forearm are associated with significant morbidity, mortality and reduced quality of life, which can be attributed not only to the fractures themselves but also to the high prevalence of comorbidities.^{5,6}

Osteoporosis is diagnosed by measuring the bone mineral density (BMD) of the hip and spine with dual-energy X-ray absorptiometry (DEXA).⁷ BMD can be assessed using quantitative computed tomography, but it is limited by radiation exposure

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and cost. Quantitative calcaneal ultrasonography and peripheral DEXA, which measure BMD in the heel, finger and forearm can effectively predict fracture risk and are much more portable and less expensive than central DEXA.⁸ The World Health Organization (WHO) defines osteoporosis as a BMD that is 2.5 standard deviations or more below the average for young healthy women.⁶

Since estrogen is essential for maintaining bone health, postmenopausal women have a higher prevalence of osteoporosis and associated fractures than older men. A 60-year-old woman has an approximately 44% lifetime risk of fracture, which is nearly double the 25% risk for a man of the same age.³ The prevention and treatment of postmenopausal osteoporosis may involve a variety of non-pharmacologic approaches.⁹ Certain osteoporosis risk factors in postmenopausal women can be reversed by modifying their lifestyle, for instance through exercise, smoking cessation and reducing the consumption of caffeine and alcohol. Regular weight-bearing activity and a balanced diet with appropriate calcium and vitamin D consumption are the main two lifestyle changes that can reduce the risk of fracture in postmenopausal women. Other modifiable lifestyle variables important for bone health and lowering fracture risk include not smoking, weight management, reduced alcohol intake and precautions for potential falls at home.^{10,11} For people with osteoporosis who are at risk for falls and fractures, improving lighting at home, removing obstacles from the home that can cause falls and using undergarments with hip protectors are advised. Resistance training and weight-bearing exercises are suggested for postmenopausal women because they help to maintain their BMD.¹² Although lifestyle changes alone may not be sufficient to prevent bone loss or reduce fracture risk, particularly in high-risk groups, they do provide an important foundation along with pharmacologic approaches to prevent or treat osteoporosis.¹³ Therefore, it is very important to incorporate lifestyle modification interventions in the mild stage of osteoporosis and osteopenia so that further complications can be prevented.¹⁴

Healthcare providers play a crucial role in the management of osteoporosis with regard to exercise training and client education in maintaining bone density. Exercise programmes are effective in improving the bone mineral density of postmenopausal women.¹⁵ In addition, knowledge and belief changes in osteoporotic women can be facilitated by brief written educational materials.¹⁶ A successful home rehabilitation programme typically depends on maintaining a regular exercise schedule, which is strongly influenced by self-motivation and

other extrinsic factors.¹⁷ In addition, it is well known that non-adherence to pharmacological treatment in osteoporosis is a concern and there is evidence that a group-based educational programme and multi-component approach interventions would improve patients' adherence to medical treatment.^{18,19} However, studies that focus on comprehensive lifestyle modification interventions along with patient education were not available in the Indian context. This study, therefore, hypothesised that taking part in a lifestyle modification intervention programme (LMIP) will increase the bone mineral density of postmenopausal women with osteoporosis in light of the literature that is currently available.

Methods

This randomised control trial was conducted at the osteoporosis clinic of the outpatient department of the Kasturba Hospital, Manipal, India, from January 2019 to December 2021.

Inclusion criteria were postmenopausal women who attended the osteoporosis clinic and were within the age group of 45–65 years, could speak and understand English or Kannada and whose BMD score was between -1 and -3. Postmenopausal osteoporotic patients who had a history of fractures and were admitted to the hospital were excluded from the study.

The sample size was calculated using the following formula for two independent groups:

$$n = \frac{2[Z_{1-\alpha/2} + Z_{1-\beta/2}]^2 \sigma^2}{d^2}$$

where $Z_{1-\alpha/2}$ is 1.96 at a 95% confidence interval; $Z_{1-\beta/2}$ is 0.84 at the power of 80%; σ is the standard deviation (56.78); and d is the clinically significant difference (40.68).

Considering the 30% attrition rate, a total sample size of 120 was calculated with 60 in each of the intervention and control groups (standard deviation and clinically significant difference were computed based on the pilot study findings).

Data collection was done after obtaining written informed consent. A stratified block randomisation method was used to allocate the sample. Strata were developed based on the age groups (i.e. 45–55 years and 56–65 years) and there were 12 total blocks, with 10 samples in each block. Random numbers were created using a computer. The allocation concealment was done by using sequentially numbered opaque sealed envelopes (SNOSE) and was prepared by an external member who was not directly involved in the study.

Bone mineral density was measured by a portable ultrasound bone densitometer (Sunlight Mini Omni Bone Sonometer with a frequency of 1.25MHz) at the wrist region by a technician at the outpatient departments. The baseline information was collected by a structured demographic questionnaire. Intervention group participants received the LMIP. The detailed process of the randomised, controlled trial is given in Figure 1.

The LMIP was based on three pillars: physical activity, health education (behavioural change communication) on exercise, diet and follow-up and motivation for sustenance. It included the components of exercise teaching, self-learning of exercises through videos, a brochure on osteoporosis management, motivational videos on the management of osteoporosis, reminder messages and regular phone calls as a follow-up and motivation to adhere to the lifestyle modification intervention. The LMIP was developed by adopting a meticulous programme development approach including an extensive review of the literature, designing of the programme, experts' advice, validation of the programme and piloting of the programme. The exercises included in LMIP were stretching exercises, wall push ups, toe lifts, sitting on a chair and standing up and stepping up and down. The researcher taught these exercises to each participant individually in the outpatient department. The same exercise video prepared by the researcher was sent to the postmenopausal women's mobile phones. In addition, health education on osteoporosis and its management was provided. The participants were also given a brochure on postmenopausal osteoporosis

management, which comprised a brief explanation of the disease condition, signs and symptoms, diagnosis, follow-up, exercise and dietary management. Researchers used mobile phones to deliver weekly messages and fortnightly calls, as well as motivational videos, to emphasise the consistency of LMIP.

Follow-ups for BMD were carried out at three and six months. However, there were dropouts for follow-ups due to COVID-19 and lockdown.

The control group received the standard pharmacological treatment by the physician as per the hospital protocol. They were allowed to perform their daily activities without any restriction up to the end of the study (six months). After this, the control group participants were provided with the same LMIP that was received by the experimental group.

The data were coded and analysed using the Statistical Package for Social Sciences (SPSS) Version 22 (IBM Corp. Armonk, New York, USA). Descriptive and inferential statistical tests were used for the analysis. Homogeneity among the intervention and control groups at baseline was tested using the chi-square test. If the frequency cells were less than five, then Fisher's exact test was considered. The Shapiro-Wilk test was used to determine normal distributions. As the data were not normally distributed, non-parametric tests were used for statistical analysis. Differences between groups were analysed using the Mann-Whitney U test. The Wilcoxon signed-rank test was used to analyse the change in BMD at baseline and three and six months. A *P* value of less than 0.05 was considered significant.

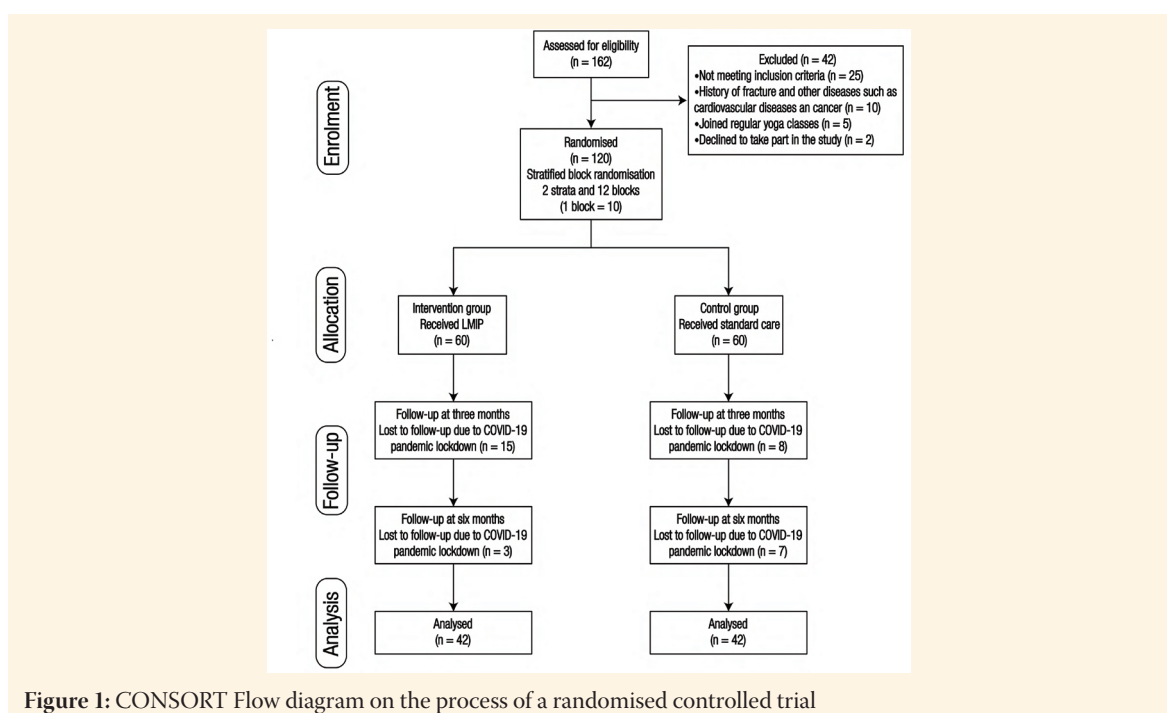


Figure 1: CONSORT Flow diagram on the process of a randomised controlled trial

Table 1: Frequency and percentage distribution of demographic characteristics of participants (N = 120)

Variable	n (%)			P value
	Experimental group (n = 60)	Control group (n = 60)	Overall	
Mean age in years \pm SD	56.8 \pm 2.5	55.7 \pm 1.8	-	
Occupation				0.242
Daily labour	1 (1.7)	2 (3.3)	3 (2.5)	
Housewife	44 (73.3)	41 (68.3)	85 (70.8)	
Others (government and private jobs)	15 (25.0)	17 (28.3)	32 (26.6)	
Number of children				0.332
1	9 (15.0)	6 (10.0)	15 (12.5)	
2	24 (40.0)	27 (45.0)	51 (42.5)	
3	17 (28.3)	20 (33.3)	37 (30.8)	
\geq 4	10 (16.7)	7 (11.7)	17 (14.2)	
Number of members in the family				0.561
1-4	34 (56.7)	36 (60.0)	70 (58.3)	
\geq 5	26 (43.3)	24 (40.0)	50 (41.7)	

SD = standard deviation

Table 2: Mann Whitney U value computed for pre-test, post-test I and post-test II of BMD scores among intervention and control groups (N = 120)

BMD measurements	Median	(Q1, Q3)	P value
Pre-test			
Intervention (n = 60)	-2.2	(-2.5, -1.8)	0.431
Control (n = 60)	-2.3	(-2.6, -1.9)	
Post-test I			
Intervention (n = 45)	-1.3	(-2.5, -1.0)	0.126
Control (n = 52)	-1.8	(-2.4, -1.5)	
Post-test II			
Intervention (n = 42)	-1.5	(-1.8, 0.65)	<0.001
Control (n = 43)	-2.0	(-2.4, -1.5)	

BMD = bone mineral density.

This trial was registered under the Clinical Trial Registry of India (CTRI) with trial no. CTRI/2019/05/019045 and ethical permission was obtained from Institutional Ethics Committee, Kasturba Hospital and Kasturba Medical College, Manipal (IEC-30-2019).

Results

In this randomised control trial, 120 postmenopausal osteoporotic women were enrolled, with 60 in each of the intervention and control groups. During the follow-

Table 3: Wilcoxon signed-rank test results to compare the change in BMD Scores within intervention and control groups from pre-test to post-test I and II (N = 120)

Bone mineral density	Z score	P value*
Pre-test to Post-test I		
Intervention (n = 60)	-5.591	<0.001
Control (n = 60)	-5.509	<0.001
Pre-test to Post-test II		
Intervention (n = 45)	-5.556	<0.001
Control (n = 52)	-5.172	<0.001
Post-test I to Post-test II		
Intervention (n = 42)	-3.626	<0.001
Control (n = 45)	3.352	<0.001

BMD = bone mineral density.

*To adjust for multiple comparisons, P-value <0.05/3 was considered statistically significant.

up after six months, 18 samples from the intervention group and 15 from the control group dropped out due to the COVID-19 pandemic and lockdown. The mean age of the intervention and control group were 56.8 \pm 2.5 and 55.7 \pm 1.8, respectively. Higher proportions of the women were housewives (70.83%). It was also found that 42.5% of the participants had two children and 58.33% had four or fewer family members [Table 1]. Homogeneity test results showed that both the intervention and control groups were homogenous ($P > 0.05$).

As the data were not normally distributed, the Mann-Whitney U test was used to compare the differences in the median pre-test and post-test scores between the experimental and control groups among postmenopausal osteoporotic women [Table 2]. The Wilcoxon signed-rank test was used to compare the change in scores from pre-test to post-test II [Table 3].

The increase in the BMD median score among the experimental group was from -2.2 (-2.5--1.8) to -1.5 (-1.8--0.65) whereas in the control group, it was from -2.3 (-2.6--1.9) to -2.0 (-2.4--1.5). The increase in the median score of the experimental group (0.7) was higher than in the control group (0.3). The results of the Mann Whitey U test showed a statistical significance between the intervention and control groups in post-test II ($U = 505.5$; $P < 0.05$).

A Wilcoxon signed-rank test was computed to observe the change in BMD scores within intervention and control groups from pre-test to post-test I and II. The findings revealed a significant change in both the intervention and control groups from pre-test to post-test I and post-test II ($P < 0.001$). Hence, it can be concluded that the LMIP was very effective in increasing bone mineral density among postmenopausal women with osteoporosis.

Discussion

The study aimed to investigate the effectiveness of the LMIP on the BMD of postmenopausal osteoporotic women. In this study, lifestyle modification interventions were provided along with pharmacological treatment for the intervention group. The study results demonstrated that the LMIP improved the BMD of the postmenopausal osteoporotic women in comparison to the control group, which received only pharmacological treatment. This may be explained by the fact that the integration of lifestyle modification components along with pharmacological treatment, including exercise, regular physical activities, dietary management, reinforcement of treatment and follow-up, may have influenced the improvement of the BMD. It is significant that the LMIP was deemed safe because, over the course of the study, no injury incidences were reported. Additionally, regular phone calls for follow-up monitoring may have encouraged participants to accomplish the activities. Health education provided by the researcher motivated them to adhere to the therapy positively and had great enthusiasm for performing the activities.

The study findings were consistent with a study that had an eight-week physiotherapeutic education on back extensor muscle strength, physical performance,

balance and quality of life in postmenopausal women.²⁰ In addition, the study findings were similar to a study where osteoporotic women underwent a six-month personalised drug therapy and focused mechano-acoustic vibration, which had a beneficial effect on BMD.²¹ Another study also reported a significant increase in the bone mineral density of the participants after an intervention programme, which included physical activity and diet supplementation.²² Similarly, many other studies conducted on the effect of different exercises on bone mineral density found them to be effective.^{23,24} There is evidence that increasing physical exercise improves bone mineral density.²⁵ Furthermore, there were independent studies and reviews on the impact of dietary management on risk reduction and better prognosis for osteoporosis.^{26–28} In addition, there was a study, which evaluated the impact of osteoporosis education on osteoporosis knowledge and calcium intake.²⁹ There were a few systematic reviews conducted on the impact of exercises on bone mineral density.^{30,31} As per the results of the systematic review, exercise could be a safe and effective strategy to prevent bone loss in postmenopausal women.³²

There was a dearth of studies to compare the integration of lifestyle modification interventions with pharmacological treatment, including exercise, dietary management, reinforcement of treatment and follow-up. Furthermore, reinforcement and motivation were integrated into the study through periodic phone calls and messages. Individual counselling and educational sessions were found to be essential to motivate middle-aged women in their menopause. This session helped participants by clarifying their doubts. Thus, as the findings of this study were encouraging, there is now a reason to undertake extensive research along similar lines.

Osteoporotic fractures are the third-leading cause of disability. Therefore, maintaining strong bones is essential for extending a healthy lifespan. As various factors including diet, exercise, consumption of alcohol and tobacco products and genetics, have an impact on bone mass, it is very important to maintain bone health and prevent complications by adopting a diet rich in balanced nutrients, including calcium, vitamin D and protein, as well as through regular exercise and smoking cessation. The results of this study are supported by previous literature and showed that lifestyle modification interventions along with pharmacological treatments among postmenopausal osteoporotic women were effective in bringing positive results.^{13,33} Thus, it is suggestive of the integration of lifestyle modifications in clinical practice while treating post-menopausal osteoporotic patients.

There are several limitations to this study. First,

the participants in the experimental group would have discussed the intervention with the control group. However, for the intervention group, participants' intervention was provided in a separate room. Second, there was no monitoring at home for compliance with the LMIP. However, the LMIP developed for this study was simple, low-cost and convenient for postmenopausal women to practice at home. Third, despite the fact that DEXA is regarded as the gold standard for the diagnosis of osteoporosis, BMD was measured using the ultrasound method in this study since it was affordable and feasible for the researchers. Finally, the data collection was carried out during the COVID-19 pandemic and lockdown, so the study lost some of the postmenopausal women to follow-up. However, the sample size was more than the estimated size which resulted in reliable data analysis.

Conclusion

The study revealed that lifestyle modification along with pharmacotherapy for postmenopausal osteoporotic women was found to be effective. Regular implementation of this programme for women with primary osteoporosis who haven't experienced any fracture yet will help reverse the bone loss and bone health could be improved. Clinicians and nurses should focus on lifestyle modification interventions in addition to pharmacotherapy because it is cost-effective and affordable for patients in preventing the most severe complications such as fractures.

AUTHORS' CONTRIBUTION

ADS, JAN and KKVA conceptualised and designed the study. ADS collected the data and RN analysed the data. ADS, BSN and MP drafted the manuscript. JAN and KKVA supervised the work and edited the manuscript. All authors approved the final version of the manuscript.

CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest.

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