

Efficacy of Comprehensive Management Protocol for Improvement of Bone Health in Elderly Osteoporotic Individuals Attending a Tertiary Care Centre Hospital in Kolkata, India

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ABSTRACT

Background: Osteoporosis is a growing public health concern, especially among the elderly population in India. There is a dearth of studies evaluating the role of multimodal treatment for the improvement of bone health apart from pharmaceutical management in India. In this study, an attempt was made to improve bone health using comprehensive multimodal management, compared to conventional pharmaceutical management, specific nutrition, and diet. **Methods:** A total of 130 patients diagnosed with osteoporosis (T score -2.5 or below by Quantitative Ultrasound Scan, QUS), aged between 50 to 80 years, were selected for the study. All participants were receiving standard pharmaceutical treatment along with specific nutrition and diet prescribed by their treating physician. They were randomly divided into two groups of 65 each: the control group continued with standard treatment, while the experimental group received comprehensive management (including standard care, muscle-building exercises, and environmental/lifestyle modifications). Data were collected from 58 participants in each group. Bone Mineral Density (BMD) was measured via QUS at baseline on the 6th months and 12th months, with follow-up at 3 and 9 months via telephonic interview, mainly for supervision. Statistical analysis was performed using the Mann-Whitney U test. **Results:** At baseline, median BMD T score was -2.5 (control) vs -2.6 (experimental) ($p=0.08$), indicating homogeneity. At 6 months, it remained -2.6 (control) vs improved -2.5 (experimental) ($p=0.02$). At 12 months, the score was -2.6 (control) vs -2.5 (experimental) with $p=0.001$, suggesting significant improvement in the experimental group. **Conclusion:** A supervised, comprehensive multimodal management protocol offers a cost-effective and practical adjunct to conventional pharmacological treatment. It significantly enhances bone health and BMD outcomes in elderly patients with osteoporosis.

Keywords: Bone Health; Elderly Care; Nurses; Osteoporosis

INTRODUCTION

Osteoporosis, being a multifactorial disease, needs multimodal management apart from pharmaceutical treatment for reduction of risk of future fragility fracture (Cooper, Rizzoli & Reginster, 2009). Moreover, osteoporosis is not a disease of bone only, but it also affects the muscle (Nielsen *et al.*, 2018) with a reduction of available functioning muscle fibres with weakness of axial muscles, leading to a fall on the ground by trivial trauma resulting in a fragility fracture which needs specialised management with huge financial loss, complications and comorbidities. Therefore, it is of utmost importance to screen the at-risk individuals (Tucci, 2006), especially the elderly, as osteoporosis is highly prevalent, at about 30.50% among elderly individuals in India, particularly females (Khinda *et al.*, 2022).

The basic parameter for diagnosing osteoporosis is the measurement of bone mineral density (BMD) through the assessment of the T -score. Dual-Energy X-ray Absorptiometry (DEXA) is a medical imaging technique used primarily to measure Bone Mineral Density (BMD). Though DEXA is the gold standard for measuring BMD, it is inaccessible for community screening and needs specialised technical support and

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infrastructure (Curtis *et al.*, 2020). Quantitative ultrasound scans (QUS) have the ability to accurately measure the bone mineral density (BMD) of long bones, particularly the loss of trabecular architecture (Siffert & Kaufman, 2007), which is the initial sign of osteoporosis. The pharmacological treatment is the conventional management of osteoporosis, but it needs a prolonged period of continuous intake (Cooper, Rizzoli & Reginster, 2009), for which poor compliance of drug intake by patients was noted in 33% in the first year and 22% in the second year of initiation of treatment. Apart from pharmacological measures, there is a need to increase muscle strength by specific muscle-building exercise (Dent *et al.*, 2023; Mineiro *et al.*, 2024) and also lifestyle and environmental modification (Anupama *et al.*, 2023) to prevent falls and the occurrence of fragility fractures (Dent *et al.*, 2023; Mineiro *et al.*, 2024; Anupama *et al.*, 2023).

There is a dearth of studies on the management of osteoporosis through standardised, comprehensive multimodal management protocols for susceptible individuals in India. Furthermore, nurses should take a proactive role in addressing this knowledge gap by actively participating in the screening of individuals at risk for osteoporosis. They can play a vital part in enhancing musculoskeletal health by educating patients on lifestyle modifications, promoting adherence to targeted exercise regimens, and supporting overall preventive strategies—complementing the pharmacological treatment prescribed by the physician.

Objective of this Study

To assess the bone mineral density by using an ultrasound bone densitometer at the baseline among elderly osteoporotic individuals attending orthopaedic outpatient departments

To assess and compare the changes of bone mineral density in the control and experimental groups following comprehensive and conventional management.

METHODOLOGY

Study Approach and Design

This study adopted a quantitative research approach with an experimental pre-test post-test design. The primary objective was to assess the effectiveness of a comprehensive management protocol on Bone Mineral Density (BMD) among elderly osteoporotic patients.

Study Setting

The study was conducted in the Orthopaedics Outpatient Department of Medical College and hospitals, a tertiary care centre, Kolkata, West Bengal, between April and June 2021.

Population and Sample

The study population consisted of elderly patients aged between 50 and 80 years, diagnosed with osteoporosis (defined as BMD T-score ≤ -2.5) using Quantitative Ultrasound Scan (QUS). All participants were under standard pharmaceutical treatment with specific nutritional and dietary recommendations as prescribed by their attending physicians.

Inclusion Criteria

Patients aged 50–80 years.

Diagnosed with osteoporosis based on BMD T-score ≤ -2.5 by QUS.

Willing to participate and provide informed consent.

Exclusion Criteria

Patients with secondary osteoporosis or other metabolic bone diseases.

Those unable to perform physical exercises due to severe comorbid conditions

Sample Size Calculations

Sample size calculation was done using the following formula for two independent groups.

$$n = \frac{2 \left[z_1 - \frac{\alpha}{2} + z_1 - \frac{\beta}{2} \right]^2 \alpha^2}{d^2}$$

Here $z_1 - \frac{\alpha}{2}$ is 1.96 at 95% confidence interval. $z_1 - \frac{\beta}{2}$ is 0.84 at the power of 80% (β). α is the standard deviations (56.20) and d is the clinically significant difference (42.68). Considering the 30% attrition rate, total sample size of 130 was calculated with 65 in each experimental and control groups.

In this study, 130 patients with ages between 50 to 80 years, who attended in Orthopaedic Out-patient department in Medical College and Hospital, Kolkata from April to June 2021 and diagnosed as osteoporosis individuals with BMD T score -2.5 or below by Quantitative ultrasound scan (QUS), taking standard pharmaceutical treatment with specific nutrition and diet, prescribed by attending physician, were selected for the study.

Research Tools and Data Collection

Demographic and Fall Risk Profile

To meet the first objective, a structured demographic questionnaire was used to collect data on:

Age, sex, religion, education, marital status, occupation, and place of residence

Fall history over the past 12 months and tendency to fall

Bone Mineral Density (BMD) Assessment

For the second objective, BMD was measured using T -scores obtained via Quantitative Ultrasound (QUS) with a Mini Omni ultrasound device (mHz) operated by a single trained technician to ensure consistency.

Intervention and Group Allocation

Participants were randomly assigned by the lottery method into:

Control Group ($n = 65$): Received standard pharmaceutical treatment along with specific nutrition and dietary instructions as per physician's advice.

Experimental Group ($n = 65$): Received the same treatment as the control group, along with a comprehensive management protocol, which included:

Muscle-strengthening exercises: Performed once or twice daily before meals for 30 minutes.

Lifestyle and environmental modifications: Advised to prevent falls and promote musculoskeletal health

Follow-Up and Data Collection Timeline

Baseline, 6th month, and 12th month assessments: Conducted through in-person physical visits.

3rd and 9th month assessments: Conducted via telephonic interviews.

During physical visits, exercise demonstrations were provided, and all queries were clarified. Participants were instructed to perform the exercises at home at least three or more times per week. Queries raised during telephonic interviews were addressed promptly, and participants were encouraged to report any concerns.

Statistical Analysis

The effectiveness of the intervention was assessed by comparing the median BMD T -scores between the two groups at specified intervals. Statistical analysis was performed using the Mann–Whitney U test, considering a p -value < 0.05 as statistically significant.

Out of the 130 participants, 58 patients from each group (47 females and 11 males per group) completed the study. The mean age of participants in the experimental group was 62.27 years, while that in the control group was 59.11 years.

Ethical Consideration

Ethical approval for this study was obtained from the Institutional Ethics Committee of Medical College and Hospitals, Kolkata (with reference number MC/KOL/IEC/NON-SPON/459/09-2019), on 20th September, 2019. Written informed consent was obtained from all patients who voluntarily agreed to participate in the

study.

RESULTS

A total of 130 individuals diagnosed with osteoporosis and receiving standard medical treatment, nutrition, and dietary support were enrolled in the study through block randomization and allocation concealment. Participants were randomly assigned to either the experimental group (n = 65), which received lifestyle modification (LSM) and exercise in addition to standard care, or the control group (n = 65), which received standard care only. Follow-up assessments were conducted over a 12-month period at regular intervals: at 3 and 9 months via telephonic interviews using a structured questionnaire, and at 6 and 12 months through in-person assessments that included both a structured questionnaire and Bone Mineral Density (BMD) testing. Due to participant attrition during the study period, the final analysed sample comprised 58 participants in the control

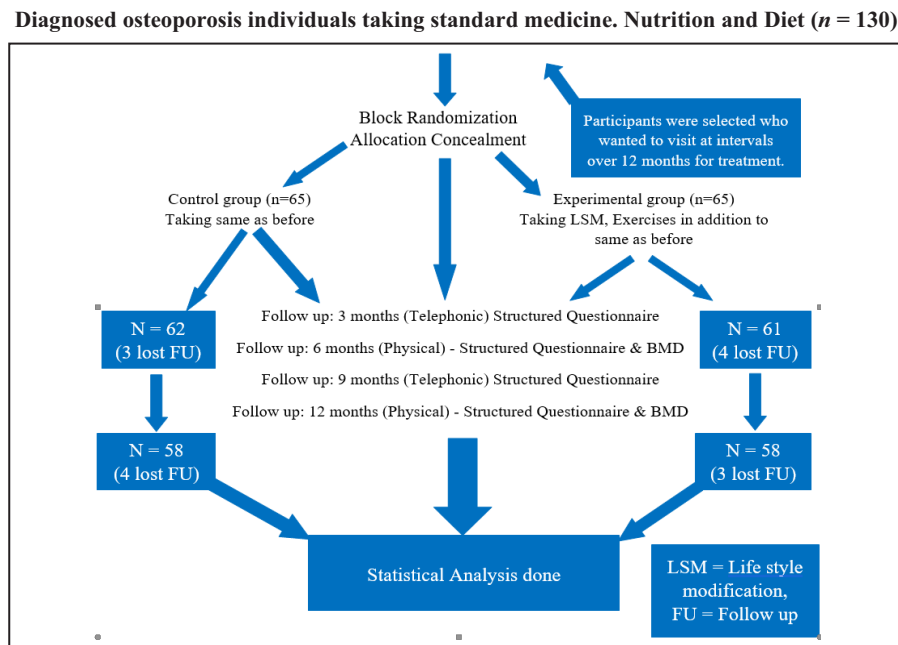


Figure 1: Study Design Showing Participant Enrolment and Assessment Points from Baseline to 12 Months

Demographic Characteristics

The demographic profile revealed that the majority of participants were elderly Hindu females from rural areas of West Bengal, educated up to secondary level, moderately active, and married.

Table 1: Finding Related to Description of the Study Participants (Frequency and Percentage Distribution of the Socio-Demographic Variables) n=116(n_c + n_e)

Variable	Control Group (n = 58)	Experimental Group (n = 58)
Age (Mean ± SD)	59.11 ± 7.18	62.27 ± 7.66
Sex (F/M)	47 (81.03%) / 11 (18.96%)	47 (81.03%) / 11 (18.96%)
Religion	Hindu: 53 (91.37%) Muslim: 5 (8.62%)	Hindu: 54 (93.10%) Muslim: 4 (6.89%)
Education	Primary: 12 (20.68%) Secondary: 27 (46.55%) Higher: 19 (32.75%)	Primary: 11 (18.96%) Secondary: 26 (44.82%) Higher: 21 (36.20%)
Occupation	Active: 3 (5.17%) Moderately Active: 42 (72.41%) Sedentary: 13 (22.41%)	Active: 8 (13.79%) Moderately Active: 37 (63.79%) Sedentary: 13 (22.41%)
Marital Status	Married: 46 (79.31%) Unmarried: 3 (5.17%) Widowed: 9 (15.51%)	Married: 48 (82.75%) Unmarried: 0 (0%) Widowed: 10 (17.24%)
Residence	Rural: 11 (18.96%) Urban: 47 (81.03%)	Rural: 13 (22.41%) Urban: 45 (77.58%)

Bone Mineral Density (BMD) Comparison

Statistical analysis was performed using Python and Microsoft Excel. The Shapiro-Wilk test indicated non-normal distribution, prompting the use of the Mann-Whitney U test. At baseline, both groups had similar BMD (*T*-scores), indicating initial homogeneity. However, significant improvement was observed in the experimental group at both the 6-month and 12-month follow-ups.

Table 2: Comparison of Median Value of BMD (*T* Score) between the Control and Experimental Group by Mann Whitney Test

Time Point	Control Group (Median, Q1–Q3)	Experimental Group (Median, Q1–Q3)	Mann Whitney U	<i>p</i> -value
Baseline	-2.5 (-2.6, -2.5)	-2.6 (-2.7, -2.5)	4709.5	0.08 (NS)
6 months	-2.6 (-2.65, -2.5)	-2.5 (-2.7, -2.5)	6362.5	0.02*
12 months	-2.6 (-2.7, -2.6)	-2.5 (-2.6, -2.3)	7985.5	0.001**

*Significant at $p < 0.05$; **Highly significant at $p < 0.01$; NS = Not Significant

Percentage Change in BMD Over Time

Figure 2 shows the change in mean BMD (*T*-score) at baseline, 6 months, and 12 months between groups. The percentage improvement in BMD was significantly higher in the experimental group at 12 months, supporting the positive impact of lifestyle modifications and exercise in addition to standard treatment.

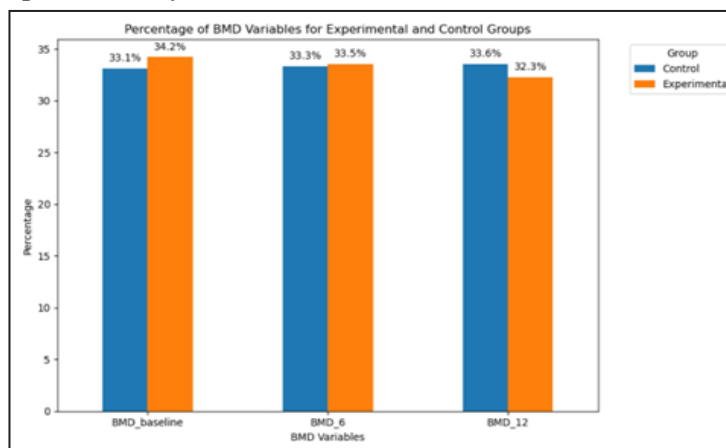


Figure 2: Comparative Change of Mean Value of BMD between Control And Experimental Group at Base Line, 6 and 12 Months Follow Up

DISCUSSION

Majority of the population became homebound during the covid period. The bone mineral density (BMD) is a reliable parameter for the diagnosis of osteoporosis and is used to check the effectiveness of osteoporosis management, as suggested by another author (Lee *et al.*, 2024). In this study, quantitative ultrasound scans were used to determine changes in BMD (*T* score), as ultrasound can detect the internal trabecular architectural loss of long bones, which comes earlier in osteoporosis (Hans & Baim, 2017; Lee *et al.*, 2024). Furthermore, the same machine was used by a single Additionally, the same machine was operated by one technician to measure the *T* score at the start and during regular follow-up visits in both groups of the study to prevent mistakes and bias.

The demographic profile suggested the homogeneity of both the groups at the base line (Table1). Osteoporosis was found among educated, elderly, relatively less active females of urban populations, indicating the fulfilment of our first objective of justification of the need for screening for osteoporosis even in relatively developed areas of society and the possibility to improve their knowledge by advice and practice by demonstration of techniques, specially of specific exercises , as supported by other experience (Tucci, 2006; Lee *et al.*, 2024).

In the experimental group, adding supervised non-pharmacological measures with conventional

pharmaceutical treatment along with specific nutrition and diet as suggested by another author (Eastell *et al.*, 2019) showed a change of *T* score from the 6th month with statistical improvement ($p = 0.02$ of Table 2) to the 12-month follow-up ($p = 0.001$ of Table 2) in comparison to that of the control group. Furthermore, the percentage of BMD did not show significant change in the control group from the baseline value of 33.1% to that of 33.6% at 12 months (Figure 2). This shows that relying only on medication for treating osteoporosis isn't enough, possibly because patients often don't take their medicines regularly for long periods, as noted by other studies (Cooper, Rizzoli & Reginster, 2009) and supports our findings that adding non-drug treatments is beneficial.

Strengthening the muscles of the lower back, abdomen, thighs, legs, and feet (Dent *et al.*, 2023), along with lifestyle and environmental modifications such as avoidance of smoking, alcohol, and proper walking aids, were part of the comprehensive management protocol in this study. This protocol also included measures like lighting staircases and removing rugs to prevent falls in the home (Anupama *et al.*, 2023). These interventions, supervised at regular intervals without additional costs, significantly improved musculoskeletal strength, balance, and coordination (Dent *et al.*, 2023; Mineiro *et al.*, 2024). These findings emphasize the importance of targeted educational interventions focusing on socio-demographic factors such as education, ethnicity, and menopausal history to improve osteoporosis prevention in this community (Bhattarai, 2024). There is need for consistent international protocols to improve the cost-effectiveness and quality of osteoporosis care, particularly for postmenopausal women (Rentzeperi *et al.*, 2023). Thus the healthcare providers must critically evaluate and adapt exercise recommendations to optimize rehabilitation outcomes for individuals with osteoporosis (Agostini *et al.*, 2024).

Therefore, comprehensive management protocol effectively changed BMD over 6 months (33.5% in comparison to 34.2% at baseline at Figure 2) and 12 months (32.3% in comparison to 34.2% at baseline at Figure 2 follow-up), and thus improvement of BMD can reduce the risk of fragility fracture, extra-skeletal injury and pain associated with osteoporosis, thus improving the quality of life, as supported by other authors (Lee *et al.*, 2024; Anish & Nair, 2024) and fulfilled our second objective. Additionally, regular check-ins, both in person and by phone, helped people stick to their osteoporosis management plan and made it more effective, as shown by other researchers (Lata & Kaur, 2023; Elam *et al.*, 2024). A study underscores significant barriers in osteoporosis management, including limited knowledge of guidelines and medication options, as well as financial constraints among patients. Additionally, adhering to Clinical Practice Guidelines highlights its potential for broader implementation to enhance osteoporotic patient care outcomes (Muhamad Jamil *et al.*, 2024). This addition of non-pharmaceutical measures without additional financial burden, along with supervision at regular intervals, is within the capacity of nursing personnel, which can be implemented at primary health setups, as reported from another study (Nuti *et al.*, 2019). These findings suggest that such interventions can significantly improve the quality of life for community-dwelling older adults, reflecting the importance of culturally tailored healthcare approaches (Deng *et al.*, 2025).

Limitation

The study period of 12 months is a limitation, as a longer period may be required to find the effectiveness of pharmaceutical treatment, as suggested by other authors. But patient compliance was a real challenge in this study, for which telephonic follow-up was added. This increased the mental support of elderly at-risk patients with osteoporosis in the urban area of ultra-nuclear families, thus increasing acceptance and helping the improvement of BMD. Future studies with extended follow-up durations and larger sample sizes could provide more comprehensive evaluation of long-term treatment effectiveness and sustainability of combined interventions.

CONCLUSION

Pharmacological treatment by the treating physician is the conventional management of osteoporosis, commonly seen among elderly females. But as medicines need a longer duration of intake, it fails to show an optimum outcome, predominantly from poor patient compliance. As the Supervised Comprehensive management protocol does not cost anything extra and can be provided by any healthcare professional; therefore, it might work better alongside medication to help improve bone health in older adults at risk for osteoporosis, making it a good option for managing the condition.

Recommendation

Furthermore, an electronic version of advice and instructions can be made in the future for monitoring such patients across larger populations at risk in different geographical areas.

Conflict of Interest

The authors have no conflict of interest for the conduction of study.

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