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Effect of Life-Style 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 helps to revert the bone loss and prevent the complications. **Methods:** A randomized 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 for the study. The total sample size of the study was 120 with 60 in each of the experimental and control group. After obtaining the informed consent, stratified block randomization method was used to allocate the participants to intervention and control group. 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 Lifestyle Modification Intervention Program (LMIP) whereas control group received the standard regular care by 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)] where as 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 Mann Whitey U test showed a statistical significance between the intervention and control groups in the post test after 6 months ($U = .505.5$, $p<0.05$). Wilcoxon signed rank test showed the 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 in regular therapy.
Keywords: LMIP, postmenopausal women, bone health status, bone mineral density

Advances in Knowledge

- Effective lifestyle modification intervention was efficient in improving the Bone Mineral Density of Postmenopausal women with osteoporosis
- The constant encouragement and motivation endure lifestyle modification
- Counselling and education are imperative to improve the bone health status of the postmenopausal women

Application to Patient Care

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

Introduction

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 older population and an improvement in life expectancy, osteoporosis is becoming a worldwide epidemic. According to estimates, more than 200 million individuals worldwide have osteoporosis[3], and one in three women over 50 and one in five men may experience osteoporotic fractures at some point in their lifetime[4]. These fractures, which primarily occur at the hip, vertebrae, and distal forearm [5] are associated with significant

morbidity, mortality, and reduced quality of life, which can be attributed not only to the fracture itself but also to the high prevalence of comorbidities.[6]

Osteoporosis is diagnosed by measuring BMD of the hip and spine with dual energy X-ray absorptiometry.[7] BMD can be assessed using quantitative computed tomography, but it is limited by radiation exposure and cost. Quantitative calcaneal ultrasonography and peripheral DEXA, which measure BMD in the heel, finger, and forearm and can effectively predict fracture risk, are much more portable and less expensive than central DEXA. [8] The World Health Organization defines osteoporosis as a BMD that is 2.5 standard deviations or more below the average for young healthy women.[6]

Since oestrogen 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.[9.] The prevention and treatment of postmenopausal osteoporosis may involve a variety of non-pharmacologic approaches.[10] Certain osteoporosis risk factors in postmenopausal women can be reversed by modifying one's lifestyle, for instance through exercise, smoking cessation, and reducing 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.[11,12] 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 BMD[13] 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.[14] Therefore, it is very important to incorporate the lifestyle modification interventions in the mild stage of osteoporosis and osteopenia so that further complications can be prevented. [15]

Health care providers play a crucial role in the management of osteoporosis with regard to the exercise training and client education in maintaining the bone density. Exercise programmes

have been found to be effective in improving the bone mineral density of postmenopausal women. [16]Also, knowledge and belief changes in osteoporotic women can be facilitated by brief written educational materials. [17]A successful home rehabilitation programme typically depends on maintaining a regular exercise schedule, which is strongly influenced by self-motivation and other extrinsic factors[18] In addition, it is well known that non-adherence to pharmacological treatment in osteoporosis is a concern[19] and there is evidence that a group-based educational programme and multicomponent approach interventions [20]would improve patients' adherence with medical treatment. However, the studies that focus on comprehensive lifestyle modification interventions along with patient education were not available in the Indian context. We therefore hypothesise that taking part in a lifestyle modification intervention programme will increase the bone mineral density of postmenopausal women with osteoporosis in light of the literature that is currently available.

Methods

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

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

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 fracture and were admitted to the hospital were excluded from the study.

Sample size was calculated using the formula for two independent groups.

$$n = \frac{2[Z_1\text{-}\alpha/2 + Z_1\text{-}\beta/2]^2\,\sigma^2}{d^2}$$

Where

Z_1-$\alpha/2$ is1.96 at a 95 % confidence interval.

Z_1- $\beta/2$ is 0.84 at the power of 80%

σ is the standard deviation (56.78)

d is the clinically significant difference (40.68)

Considering the 30% attrition rate, a total sample size of 120 was calculated, i.e. 60 each in of the intervention and control group was included (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 randomization 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 it was prepared by an external member who was not directly involved in the study.

Bone mineral density was measured by portable ultrasound bone densitometer (Sunlight Mini Omni Bone Sonometer with 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 Lifestyle Modification Intervention Programme (LMIP). The detailed process of RCT 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, and motivational videos on 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 program development approach including an extensive review of literature, designing of the program, experts' advice, validation of the program and piloting of the program. The exercises included in LMIP were stretching exercises, wall pushups, toe lifts, sitting on a chair and getting up, and stepping up and down. The researcher taught these exercises to each participant individually in the outpatient department. The same exercises 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 texts and fortnightly calls, as well as motivational videos, to emphasize 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 (6 months). After which, the control group participants were provided with the same LMIP that was received by the experimental group.

Statistical analysis

The data were coded and analysed using SPSS 22. Descriptive and inferential statistical tests were used for the analysis. Homogeneity among the intervention and control groups at baseline was tested using 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 was 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 at 3 and 6 months. *p* value of less than 0.05 was considered significant.

Results

Demographic characteristics

In this randomized control trial, 120 postmenopausal osteoporotic women were enrolled, with 60 in each of the intervention and control groups. During the follow up after six months, 18 sample from the intervention group and 15 from the control group were dropped out due to the COVID-19 pandemic and lockdown. The mean age of the intervention and control group were 56.8 (SD=2.5) and 55.7 (SD=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 ($p>0.05$)

Effectiveness of lifestyle modification intervention on bone mineral density

As the data was not normally distributed, 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)] where as 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 Mann Whitey U test showed a statistical significance between the intervention and control groups in the 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 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 LMIP was very effective in increasing the bone mineral density among the postmenopausal women with osteoporosis.

Discussion

We aimed to investigate the effectiveness of LMIP on the BMD of postmenopausal osteoporotic women. In our study, lifestyle modification interventions were provided along with the pharmacological treatment for the intervention group. Our 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. The health education provided by the researcher motivated them to adhere to the therapy positively and have great enthusiasm for performing the activities.

Our study finding is consistent with a study that had 8-week physiotherapeutic education on back extensor muscle (BEM) strength, physical performance, balance, and QOL in postmenopausal women[21]. In addition, our findings are similar with a study where osteoporotic women underwent a 6-month personalized drug therapy and focused mechanoacoustic vibration which had a beneficial effect on BMD[22]. 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[23]. Similarly, many other studies conducted on the effect of different exercises on bone mineral density found them to be effective.[24,25] There is evidence that increasing physical exercise improves bone mineral density.[26] Furthermore, there were independent studies and reviews on the impact of dietary management on risk reduction and a better prognosis for osteoporosis.[27] [28] [29] In addition, there was a study which evaluated the impact of osteoporosis education on osteoporosis knowledge and calcium intake.[30] There were few systematic reviews conducted on the impact of exercises on bone mineral density. As per the results of the systematic review, exercise could be a safe and effective strategy to prevent bone loss in postmenopausal women. [31]

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 the 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 with a nutritious diet rich in balanced nutrients, including calcium, vitamin D, and protein, as well as through regular exercise and quitting smoking. Our study results are supported by previous literature, showed that lifestyle modification interventions along with the pharmacological treatments among the postmenopausal osteoporotic women were effective in bringing the positive results. Thus, it is suggestive of the integration of lifestyle modifications in clinical practice while treating post-menopausal osteoporotic patients.

Limitations

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 LMIP. However, the LMIP developed for this study was simple, low-cost, and convenient for the 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 study. Finally, the data collection was carried out during the COVID-19 pandemic and lockdown, so we missed some of the postmenopausal women for the follow up. However, the sample size was more than the estimated sample size and we could manage the analysis.

Conclusion

The study revealed that lifestyle modification along with pharmacotherapy for postmenopausal osteoporotic women was found to be effective. Regular implementation of this program for women with primary osteoporosis who haven't experienced the fracture yet will definitely help to 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 to prevent the most severe complications such as fracture.

Authors' Contribution

ADS, JAN, KKVA conceptualized and designed the study. ADS did the data collection and involved in the manuscript writing. JAN and KKVA supervised the work and edited the manuscript. BSN and MP contributed to manuscript writing. RN was involved in data analysis. All authors approved the final version of the manuscript.

Conflict of Interest

The authors declare no conflicts of interest .

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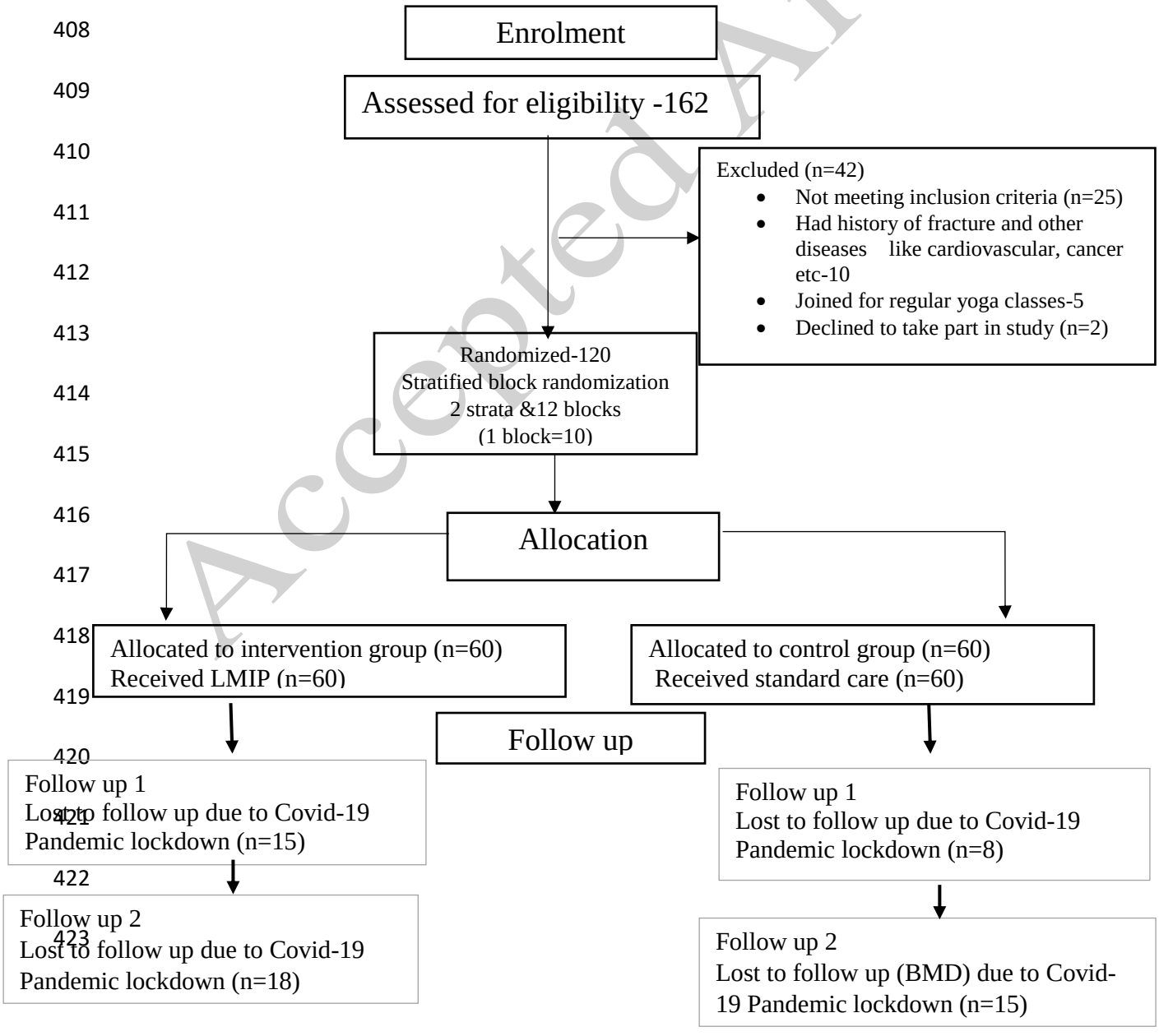

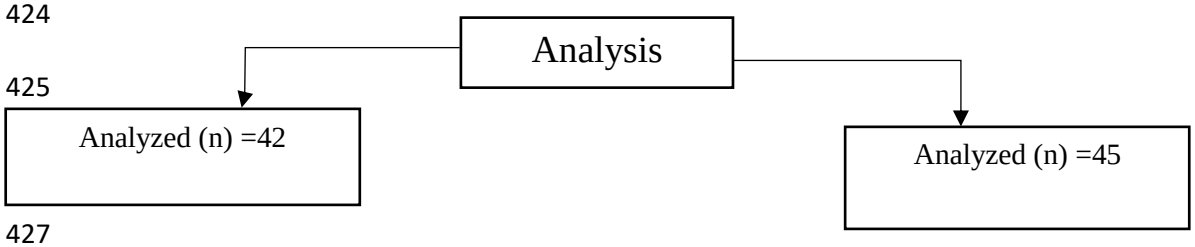

Figure 1: CONSORT Flow diagram on Process of Randomized Controlled Trial

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

Variable		**Experimental group (n=60)**		**Control group (n=60)**			**Overall**		**P value**
	Mean (SD)	Frequency (f)	Percentage (%)	Frequency (f)	Percentage (%)	Mean (SD)	Frequency (f)	Percentage (%)	
Age in years	56.8 (2.5)					55.7 (1.8)			
Occupation									0.242
Daily labour		1	1.7	2	3.3		3	2.5	
Housewife		44	73.3	41	68.3		85	70.83	
Others (govt. and private jobs)		15	25.0	17	28.3		32	26.66	
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	30.83	
≥4		10	16.7	7	11.7		17	14.17	
Number of members in the family									
1-4		34	56.7	36	60		70	58.33	0.561
5 and above		26	43.3	24	40		50	41.66	

Table 2: Mann Whitney U value computed for pre-test, post-test 1 and post-test II of BMD scores among intervention and control group

BMD measurements	Group	N	Median	(Q_1, Q_3)	P value

Pre-test	Intervention	60	-2.2	(-2.5, -1.8)	0.431
	Control	60	-2.3	(-2.6, -1.9)	
Post-test 1	Intervention	45	-1.3	(-2.5, -1.0)	0.126
	Control	52	-1.8	(-2.4, -1.5)	
Post-test II	Intervention	42	-1.5	(-1.8, 0.65)	<0.001
	Control	43	-2.0	(-2.4, -1.5)	

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.

BMD	Groups	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

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