ORIGINAL ARTICLE

Effects of high-intensity multi-modal exercise training (HIT-MMEX) on bone mineral density and muscle performance in postmenopausal women. A Pilot randomized controlled trial

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Abstract

Objectives: To determine the effects of high-intensity multimodal exercise training on bone mineral density and muscle performance in postmenopausal women.

Method: The two-armed, parallel, pilot randomised controlled trial was conducted from November 2020 to July 2021 at Riphah Rehabilitation Centre, Rawalpindi, Pakistan, and comprised women aged 45-70 having been in the post-menopause phase for at least 3 years, with body mass index <30, community ambulant and willing to have exercise therapy. The subjects were randomised into two equal groups. The experimental group A received supervised high-intensity resistance, weight-bearing, balance and mobility training twice weekly for 8 months. The control group B received low-to-moderate intensity exercises. Femoral neck and lumbar spine bone mineral density (g/cm2) were taken through a dual-energy X-ray absorptiometry scan. Muscle performance was measured using 1 repetition maximum for leg and trunk extensors, and 30 sec sit to stand test. Data was analysed using SPSS 21.

Results: Of the 101 women screened, 28(27.7%) were enrolled; 14(50%) in group A having mean age 53.36±6.28 years, and 14(50%) in group B having mean age 51.71±4.82 years ($p>0.05$). Group A showed significantly more improvement than group B both with respect to lumbar spine bone mineral density and muscle performance ($p<0.05$).

Conclusion: Supervised high-intensity multimodal exercise training protocol had a positive effect on lumbar spine bone mineral density and muscle performance in postmenopausal women.

Clinical Trial Number: NCT04653350

Link https://clinicaltrials.gov/ct2/show/NCT04653350

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Introduction

The postmenopausal period in a woman's life follows her final menstrual period. A recent systematic review has reported a significantly lower average menopausal age in Indian women (46.6 years), but the global range is 44.6-55 years.[1] This period marks an opportunity for taking preventive measures to enhance women's functional performance, quality of life and longevity. A decline in musculoskeletal health is a major concern after oestrogen deprivation. There is a sharp decline in bone mineral density (BMD) due to disequilibrium in the bone remodelling cycle, along with increased porosity and thinning of trabecular bones after 3-5 years of menopause.[2] The prevalence and associated complications of primary, type II osteoporosis are expected to rise in Pakistan due to the long life span after menopause, multiparity, lack of calcium diet, vitamin D deficiency, physical inactivity as well as socio-demographic factors.[3,4] A local study has reported its frequency as 20-49.3% in postmenopausal women (PMWs).[5]

In age >50 years, 1 out of 3 PMWs experience fragility fractures due to osteoporosis. Hip (17.5%), vertebra (16%) and wrist (16%) are the frequent sites of such fractures, leading to long-term disability.[6] This bone-loss is paralleled with a vicious cycle of muscle catabolism; lack of oestrogen bonding with type II muscle fibres and age-linked decline in growth hormone result in reduced muscle mass and decreased peak force generation. So, fragile bones and weak muscles augment each other negatively.[2] This dual compromise along with other factors, like poor posture, loss of balance and coordination, predisposes older individuals to fall. Literature suggests exercise as an optimal strategy to prevent and treat postmenopausal osteoporosis, affecting all fall-related risk factors, including BMD.[7-10] There is paucity of literature with structured high-intensity multimodal exercise (HIT-MMEX) strategy, including high resistance, high impact or weight-bearing, balance and mobility challenging

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activities, for PMWs. The current study was planned to fill the gap by determining the effects of HIT-MMEX training on bone density and muscle performance in PMWs.

Subjects and Methods

The pilot, two-armed, parallel, double-blinded, randomised controlled trial (RCT) was conducted at the Riphah Rehabilitation Center, Rawalpindi, Pakistan, from November 2020 to July 2021. The RCT was prospectively registered with the United States National Library of Medicine (Protocol ID: NCT04653350). After approval from the institutional ethics review board, the sample size was estimated using the current flat rule of thumb, with the assumption centred on feasibility in a parallel group trial.[11,12] The sample was raised using purposive sampling technique from free bone health camps which attracted PMWs through advertisements, flyers and social media usage. Those included were community ambulant PMWs aged 45-70 years with body mass index (BMI) <30. Those with a history of fragility fractures, taking steroids or hormone replacement therapy (HRT) for the preceding one year, diagnosed with renal disease, diabetes mellitus, hyperthyroidism, hypopituitarism or with any orthopaedic injury/condition hindering the exercises were excluded.

All the necessary safety measures were strictly ensured against coronavirus disease-2019 (COVID-19). The exercise gym was well-spaced and ventilated, rigorous cleaning and disinfecting procedures were maintained for all exercise equipment, surfaces and the floor. The participants' sessions were scheduled properly to avoid gathering. The subjects were made to wear masks, and frequent hand sanitisation was strictly practised both by the participants and the researchers.

After taking informed consent from the subjects, they were randomised into two groups using the sealed envelope method. The participants as well as the outcome assessors were kept blinded about the group randomisation. Baseline measurements of the femoral neck and lumbar spine BMD (g/cm2) through a dual-energy X-ray absorptiometry (DEXA) scan (Hologic QDR 4500, USA) were taken. Demographic and anthropometric data as well as assessment for muscle performance measures were recorded using 1 repetition maximum (1RM) for leg and trunk extensor muscles, and a 30-second sit-to-stand (STS) test.[13,14]

The intervention group A received supervised exercise training twice a week for 30-40 minutes for 32 weeks. It consisted of warm-up with cycling, a set of progressive high-intensity resistance exercises of lower extremity and trunk extensors gradually reaching more than 85% RM with 5-6 repetitions, high-intensity impact loading exercises, like drop jumps and marching in place. The static and dynamic balance exercises perturbing the centre of mass, reducing the base of support and mobility training was also part of the protocol. The control group B received a set of low-to-moderate resistance, weight-bearing and balance exercises designed as per universal exercise guidelines for the same duration. The total exercise time was a minimum of 150 min. DEXA scan was repeated after 8 months and functional assessments were taken at 3 and 6 months.

Data was analysed using SPSS 21. Data normality was checked with Shapiro-Wilk test (p>0.05). Based on data normality, independent t-test was applied for intergroup analysis of BMD as well as 30sec STS test, and Mann-Whitney-U test was applied for leg and trunk extensor strength. P<0.05 was considered statistically significant.

Results

Of the 101 women screened, 29(28.7%) were enrolled. After 1(3.4%) of the women dropped out after the first month, the study was completed by 28(96.55%). There were 14(50%) subjects in group A with a mean age of 53.36±6.28 years, and 14(50%) in group B with a mean age of 51.71±4.82 years (p>0.05) (Table-1).

Group A showed significantly more improvement than group B both with respect to lumbar spine BMD; 1.2±0.29 compared 1.01±0.16 (p<0.05). The difference was not

Table-1: Comparison of baseline characteristics between the groups.

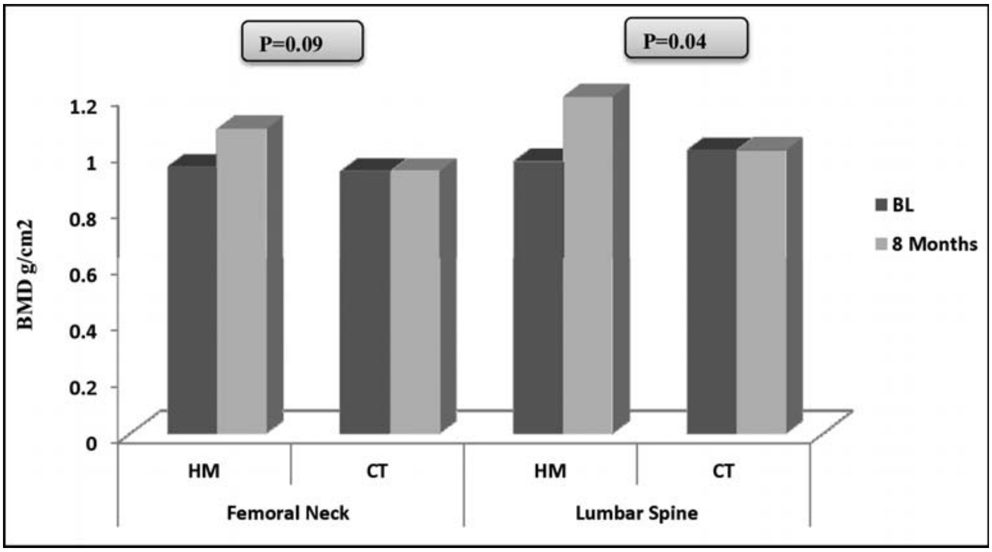
Variables	HM-Group Mean±SD	CT-Group Mean±SD	P-Value
Age (Years)	53.36±6.28	51.71±4.82	0.445
Weight (Kg)	73.20±11.84	68.07±9.57	0.219
Height (cm)	163.17±7.92	163.84±10.55	0.851
Body mass index (BMI)	26.71±3.98	25.13±3.95	0.304
Hip Circumference (cm)	70.78±29.54	67.75±32.74	0.799
Waist Circumference (cm)	58.14±28.28	50.57±28.38	0.486
Years past Menopause	7.85±5.27	7.35±5.15	0.802
Age at Menopause (Years)	45.78±6.76	44.42±5.88	0.576
Education			
Middle	3(21.43%)	6(42.85%)	
Matric	5(35.71%)	2(14.28%)	
Secondary	0(0%)	1(7.14%)	
Graduate	1(7.14%)	0(0%)	
Post-Grad	4(28.57%)	6(42.85%)	

HM: High-intensity multimodal group, CT: Control group, SD: Standard deviation.

Table-2: Inter-group analysis of muscle performance.

Variables	Time Period	Group	Med (IQR)	Mean Rank	P values
LE-1 RM (kg)	Baseline	HM	5(1)	14.64	0.914
		CT	5(1.25)	14.36	
	3 Months	HM	8(1)	10.43	0.007
		CT	9.5(1.5)	18.57	
	6 Months	HM	10.5(2)	20.50	<0.01
		CT	14(2)	8.50	
TE-1 RM (kg)	Baseline	HM	4.5(1)	13.54	0.507
		CT	5(1)	15.46	
	3 Months	HM	6.7(2)	18.93	0.004
		CT	5.25(1.5)	10.07	
	6 Months	HM	8.5(1.75)	20.68	<0.001
		CT	5.5(1.13)	8.32	
Variables	**Time Period**	**Group**	**Mean ± SD**		**P values**
30 Sec STS	Baseline	HM	10.46±1.77	-	0.34
		CT	10.71±2.01	-	
	3 Months	HM	14.71±1.54	-	0.007
		CT	12.78±1.88	-	
	6 Months	HM	18.92±2.12	-	<0.01
		CT	13.92±1.26		

LE: Leg extensors, TE: Trunk extensors, 1RM: 1 repetition maximum, HM: High-intensity multimodal group, CT: Control group, MED: Median, IQR: Interquartile range, SD: Standard deviation.



HM: High-intensity multimodal group. CT: Control group.

Figure: Inter-group analysis of bone mineral density (BMD).

significant for the femoral neck; 1.08±0.29 compared to 0.93±0.14 (p>0.05) (Figure).

There was also significant improvement regarding muscle performance in group A compared to group B (Table-2).

Discussion

The current study found positive effects of supervised HIT-MMEX training of 8 months on BMD and muscle strength in PMWs. Literature supports the effectiveness of physical activity on BMD of PMWs with low bone mass, but heterogeneity in exercise intervention has suggested further experimental trials with more robust research methods.[8] A recent meta-analysis suggested low-to-moderate improvement in areal BMD with dynamic resistance exercise using free weights for >6 months, but variation in exercise parameters resulted in inconclusive exercise recommendations for post-menopausal osteoporosis prevention or treatment.[9] In another systematic review, evidence about the favourable changes in BMD standardised mean differences were affirmed independent of the training type.[10] However, contradictory to the current findings, Rahimi et al. questioned the effects of exercise on BMD, but the inclusion of only PMWs aged >60 years might be enough justification for such diversity.[15] To generate reliable exercise recommendations, recent literature encourages more RCTs focussing on the exercise parameters.[8,10,15]

National data from observational studies stress the need for developing country-specific clinical management guidelines.[3] Amongst limited experimental studies, the researchers were able to find a single exercise-related quasi-experimental study which used a large sample size.[16] It found a positive impact of physical activity along with medication on BMD (p<0.05) of postmenopausal osteoporotic women. The finding is relatable to that of the current study, but the applied methodology of three months weight-bearing exercises was not mentioned as well as the reported BMD changes were not site-specific.[16]

High-intensity exercise training trials of sufficient duration (>6-8 months) are not common due to safety concerns of fragility fractures and participants' poor adherence to diverse exercise protocols. A trial using high-intensity resistance and impact training identified safe and efficacious to programmes for enhancing bone ($p<0.001$) at clinically relevant sites along with large group muscular performance ($p<0.001$) in PMWs.[17] These are congruent with current findings in terms of lower extremity muscle strength ($p<0.01$) and 30sec STS test ($p<0.01$). Further, a systemic review concluded multi-component high-speed exercise training along with functional tasks as promising to enhance functional outcomes.[18]

Several studies have been reported earlier with varied exercise intervention effects in PMWs with low bone mass. Yet, adherence to exercise protocol is a challenge with 50% dropout rate in the first 6 months of exercise intervention.[19] Literature supports several exercise facilitators, like less pain and fatigue, flexible exercise programme time, plan modification for knee or back pain, enjoyable environment with more social interactions and, small exercise groups supervised by a physical therapist with a positive attitude.[20] Few essential exercise barriers have also been identified, like lack of time, motivation, transportation, finances, medical conditions, fear of fall, fear of structured exercises, and being too old to participate.[20]

The current study has some limitations. Participants' adherence and regularity for exercise training were affected due to the COVID-19 pandemic. A few times, the clinical site was not accessible to the participants and women often showed reluctance to attend the sessions for COVID-19 safety reasons. Large-scale studies with the same objectives should be conducted to establish evidenced-based exercise protocol and national guidelines for persons with low bone mass.

Conclusion

Supervised and structured bone-specific high-intensity and impact exercise protocol has the potential to have a positive effect on lumbar spine bone density and muscle strength as well as performance parameters in PMWs.

Disclaimer: The text is based on an academic thesis.

Conflict of Interest: None.

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