EFFECTS OF OSTEOANABOLIC EXERCISES ON GAIT, BALANCE AND FEAR OF FALL AMONG OSTEOPOROTIC FEMALES

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Abstract- The aim of this study is to determine the effectiveness of Osteoanabolic exercises on Bone Mineral Density, Temporal-Spatial gait parameters, Gait Stability Ratio, Dynamic balance and fear of fall among the osteoporotic females. A 3-arm Randomized Controlled Trial was conducted at Department of Rehabilitation Sciences, Ziauddin Hospital using envelope method. Ninety-three osteoporotic females were randomly allocated into three groups; where group A received aerobic training protocol, group B resistance training and participant in group C had Osteoanabolic training. A Frequency Intensity Time Type protocol according to American College of Sports Medicine for aerobic and resistance training was incorporated whereas for Osteoanabolic group combination training protocol was used. Twelve weeks of training was conducted where pre and post readings were measured using activPAL, TUG, FES-I and Peripheral DEXA Scan.

Our results revealed that at 95% of confidence interval, the bone mineral density of the participants were significantly improved in all the three groups with the p-value <0.05. The gait velocity showed statistically significant result ($p<0.05$) with the highest improvement in the Osteoanabolic group (1.06±0.16 meters/sec). For dynamic balance, no clinical significant difference was found between aerobic and Osteoanabolic group although $p<0.05$ for all the groups. For fear of fall low level of concern were documented in the Osteoanabolic group (20.4±2.8) with $p<0.05$ among all the three groups. All exercise training protocols have shown improvement in gait, balance, BMD and fear of fall however, significant difference was observed in the Osteoanabolic group. Therefore, the future risk may be reduced through these training protocols.

Index Terms- Bone Mineral Density, Osteoporosis, Cadence, activPAL, Physical activity, Balance

I. INTRODUCTION:

Osteoporosis (OP), porous bone is a slow progressive disease characterized by decreased Bone Mineral Density (BMD) by micro-architectural deterioration of bone tissue (1). Therefore, leading to an increase in bone fragility that is susceptible to fracture, particularly of vertebral column, wrist and pelvis (2,3). According to International Osteoporosis Foundation (4) an estimated number of around 200 million people are present worldwide, where one out of every three women, are at a risk of having osteoporotic fracture. Similarly, OP is reported 4 times more prevalent in females (5). Among them, postmenopausal women are the most common population being affected by osteoporosis; however the condition is often asymptomatic (6)

According to WHO (World Health Organization) the prevalence of osteoporosis in postmenopausal women aged 47 to 60 years was 20.2% in lumbar vertebrae and 30% in distal radius based on the criteria using T-scores (1). In addition, the most significant decrease in BMD is about 5% per year in the first years after the menopause, followed by 1 to 1.5% per year in the following years (7).

With the increase in life expectancy, women spend more time in the post-menopausal state leading to activity limitations mostly due to high risk of fracture, fear of fall (FOF) and decrease in quality of life (6,8-9). It has been documented in literature that physical activity (PA) and exercise participation are the foundation for preventing and managing musculoskeletal diseases including osteoporosis due to its effectiveness in performing the activities of daily living (ADLs) and independence (10). A number of studies have adopted different protocols in order to improve balance to ultimately reduce the fall and improve health-related quality of life of osteoporotic individuals (11). Howe et al (12) concluded in study that progressive strengthening was found to be significantly effective type of exercise intervention on BMD, in prevention of fracture and bone loss among postmenopausal women. Physical activity exerts the mechanical forces on bone and muscle through ground reaction forces thus resulting in maintenance and gain of bone mass. However, an appropriate exercise protocol based on frequency, intensity, time, type and environment on bone health of postmenopausal women is still unspecified (13-14). The osteogenic effects of exercise are clearly site specific—that is, the effect is normally seen only in loaded bone sites, but the type, frequency, intensity, and duration of exercise that best produce the desired bone changes are not yet well determined.

Indeed in Pakistan the situation is alarming as limited data is available regarding OP along with osteopenia where 64% of women <30 years and 55% of women <45 years of age among the population of Karachi was reported (15). According to Asia Pacific Audit report Pakistan is the only country among sixteen countries where no guidelines are available for the management of osteoporosis (16). However, several physical activities and balance training programs have been implemented globally. But to the best of the author's knowledge, no studies have been conducted in the country dealing with resistance and Osteoanabolic training programs to improve BMD, gait, balance and fear of fall. Thus this study aims to determine the efficacy of osteoanabolic, aerobic and resistance exercise in improving BMD, Gait, Balance and fear of fall among osteoporotic females.

II. METHODS:

A. Study Design:

The study is single blinded, 3-arm Randomized Controlled Trial.

B. Setting & Participants:

The study was conducted in Out-Patient Department of Rehabilitation Sciences, Ziauddin Hospital (both at North and Clifton campuses). This tertiary care institution has well-established department with facilities required for a supervised exercise program.

Initially, a list of potential female candidates and the contact details were taken from the hospital database and all those who were diagnosed osteoporotic and were referred for physical therapy were invited to participate, or all those directly entering the department of rehabilitation sciences was welcomed. The invitations were sent in-person and over the telephone. The participants were given 3 working days to decide regarding their participation in the research study. Consent forms were given in both Urdu and English languages before their willingness in the study.

C. Inclusion/Exclusion Criteria: Postmenopausal osteoporotic females aged in between 50-75 years, not participating into any exercise program for past 3 months, independently ambulatory were included in the study. Red flags that limit the recruitment of participants in exercise program for example vertebral fracture, unstable heart condition, malignancy etc. were excluded from the study. Furthermore patients suffering with mental disorders and neurological disorder associated with high risk of fall such as Stroke, Parkinsonism, Dementia, Alzheimer's and other disease were not included in the study.

D. Randomization:

Participants were randomized into three groups using the ballot system to obtain equal number in each group. The two important attributes associated with concealment in randomization were fulfilled where the researcher was not allowed to predict the allocation of participant in the group neither he was allowed to change the allocation in any of the three groups. The technique involved 93 envelopes bearing the name of all three exercises such as Aerobic, Resistance and Osteoanabolic exercises, provided an equal chance to enter into any of the recommended protocol. Neither the blinding of the participant nor the therapist was possible due to the name of intervention written in the envelope. But the researcher who carried out the entire process of assessment was blinded regarding the allotment of the group by providing coding on the assessment forms.

E. Intervention:

The interventional strategies were based on 12 weeks of exercise training protocol being performed by the participants in the Physical Therapy gymnasium for the maximum of 6 days/week for Osteoanabolic group, 5 days/week for aerobic group and 3 days/ week for resistance group. The duration and intensity of exercise were as per ACSM, FITT protocol (18). The exercise protocol includes 45-60 minutes of session/ day comprising of 5-10 minutes of warm up exercises followed by conditioning exercises for 30-45 minutes and a cool down period of 5 -10 minutes. Every participant was initially assessed for resting Heart Rate and Blood Pressure.

Warm up

Warm up exercises were performed by the participants on a cycle ergometer for duration of 5 to 10 minutes. The purpose of warm up is to increase the body temperature and to raise the heart rate by 10 beats from resting heart rate.

Cool Down

The process of cool down includes 5-10 minutes including deep breathing exercises to be performed by females while sitting on comfortable chair. During this period, oxygen saturation and pulse rate was monitored; the session lasted till the pulse rate of the participant was normal to the resting heart rate.

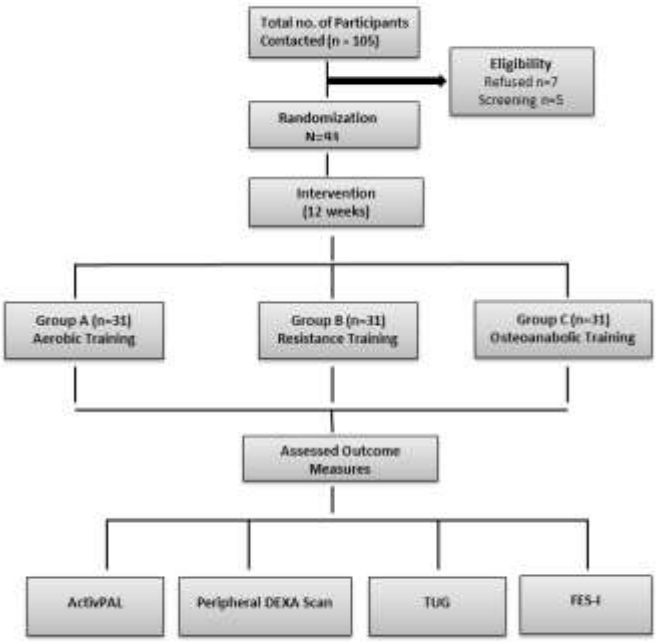

Figure 1: Flow chart depicting the framework of the study

Aerobic exercises:

Group A were advised to start walking at a comfortable speed on a treadmill for the duration of 30-60 minutes; the intensity of the exercises was 55-75% of MHR. Initially with the minimum intensity that was gradually raised up to intensity of Targeted Heart Rate (THR). Once the THR is achieved the intensity was gradually decelerated and patient proceeded for the cool down phase.

Resistance Exercises:

Group B were instructed for strengthening exercises of ten major muscle groups that include Biceps, Triceps, Pectoralis Major, Deltoid, Latissimus Dorsi, Abdominals, Back Extensors, Hamstrings, Quadriceps and Calf. The intensity of the weight bearing exercises was calculated using 1 Repetition Maximum (RM) method.

The frequency of exercises under resistance regime of training was 3 days per week, duration was 45 minutes and type includes dumbbells. The entire weight bearing protocol was divided into two halves; first half included exercises for upper limbs and second half included exercises for abdominals, back and lower limb muscles. Each group of muscles was trained for up-to three sets and each number of set involves up to 10 repetitions.

Osteoanabolic Exercises:

Group C were performed Osteoanabolic exercise training that was formulated considering the needs of the osteoporotic population. The training protocol was divided into two different

phases 'aerobic conditioning phase and resistance conditioning phase, respectively.

Phase-I: Aerobic Conditioning Phase:

Participants were instructed to walk at a comfortable speed on a treadmill for the duration of 30-60 minutes. The intensity of the exercises was 55-75% of MHR, calculated by using a Karvonen method. Initially with the minimum intensity that was gradually raised up to intensity of Targeted Heart Rate (THR). Once the THR is achieved the intensity was gradually decelerated and patient proceeded for the cool down phase. The participants performed 3 days per week for 12 weeks on alternative days.

Phase-II: Anaerobic (Resistance) Conditioning Phase:

Resistance training was started on every alternative day of the aerobic conditioning (3 days per week) for the duration of 45 minutes. The intensity of the weight bearing exercises was calculated using 1 Repetition Maximum (RM) method. Resistance training muscle and protocol was same as for Group B.

Exercise Termination Criteria:

The exercises were prematurely terminated if there is decrease in oxygen saturation below 90% during training or patient perceived exertion reached 8 on Modified Borg Dyspnea Scale. Further participants can asked to stop any time as per requested.

Outcome Measures:

Bone Mineral Density, gait velocity, cadence, GSR, balance and fear of fall were assessed at 1st day prior to treatment and on the last day post treatment.

Bone Mass Density (BMD):

BMD of the participants was measured using peripheral DXA Scan. As soon as the participant consented for the assessment and cleared the screening test, the trained technician was advised to calculate the BMD on the right sided calcaneal. In cases where the assessment could not be conducted on right side then the left sided assessment was also taken into account.

Temporal-Spatial Parameters of Gait & activPAL:

ActivPAL recorded the cadence whereas gait velocity was recorded using the Distance travelled by osteoporosis females. ActivPAL was placed in a flexible sleeve (nitrile material) and then attached on the anterior aspect of midline of thigh. Both cadence and gait velocity were calculated during the 10- meter walk test where the verbal clue of start was given to the participants and the therapist accompanied the females to prevent fall and verbal clue to maintain erect posture. The results obtained from the cadence and gait velocity was used to find the GSR Gait Stability Ratio = Cadence/Walking speed

Balance:

Dynamic balance of the females was assessed using Timed Up and Go Test. The participants were asked to be seated on comfortable chair with an arm rest. A piece of tape was placed on the floor 3 meters away from the chair so that it was easily seen by the participants. The females on the verbal cue of Go 'would stand up, walk to the line on the floor, turned around and walked back to the chair and be seated. The total duration of the activity was measured through the stop watch.

Fear of fall:

Falls Efficacy Scale-International (FES-I) consist of easy and short 16 items that estimates the level of concerns about falling during indoor and outdoor physical and social activities subsequently measured on a Likert scale, consists of four points starting from 1=not at all concerned, 2 = somewhat concerned, 3= fairly concerned to 4=very concerned. A total score is calculated ranging from 16 to 64 score in which Low Concern about falling score is 16-19; Moderate Concern about falling: 20-27 and High Concern about falling ranged in between 28-64 score

Ethical Approval:

The study is approved by The Ethical Review Committee of Ziauddin University in Karachi, Pakistan (Ref Code. 0371017AAPT). Written, informed consent was obtained from all participants included in the study. The study is conducted according to the Declaration of Helsinki.

Statistical Analyses:

Data was entered and analyzed using statistical Software MedCalc Version 18.11. Demographic and baseline information of participants were represented with frequency and distribution. Test of normality was analyzed using Skewness and Kurtosis for all outcome measures. Gait velocity, cadence, TUG and FES-I were found normally distributed, paired t test was applied for pre and post difference in all groups and ANOVA was applied for between the group analysis. Whereas BMD and GSR were not normally distributed, Wilcoxon rank test was applied for pre and post difference and Kruskal Wallis test along with post hoc was applied for between the group analyses. P-value set at <0.05 was considered significant.

III. RESULTS:

Total Ninety three participants were included, with the maximum number of the participants in between the age of 60-64 years (n=32) followed by 55-59 years of age (n=24), 65-70 years (n=18) and 50-54 (n=19), no participants were reported in the age bracket of 71 to 75 (n=0).

Wilcoxon rank test for paired samples was analyzed for BMD and GSR. As observed, the median score significantly improved BMD among the participants attending the Osteoanabolic exercise protocol when compared with both aerobic and resistance (osteoanabolic; pre: 2.6, post: 2.2 versus aerobic; pre: 2.6, post: 2.3 versus resistance; pre: 2.6, post: 2.5). The Hodges-Lehmann median difference of BMD was highest for Osteoanabolic group followed by aerobic and resistance group. The GSR was also found significant in all three groups with the median difference was highest for Osteoanabolic group (median 0.55) followed by aerobic and resistance group. At 95% of CI for median the statistically significant result was found $p< 0.05$ in all groups (Figure 2)

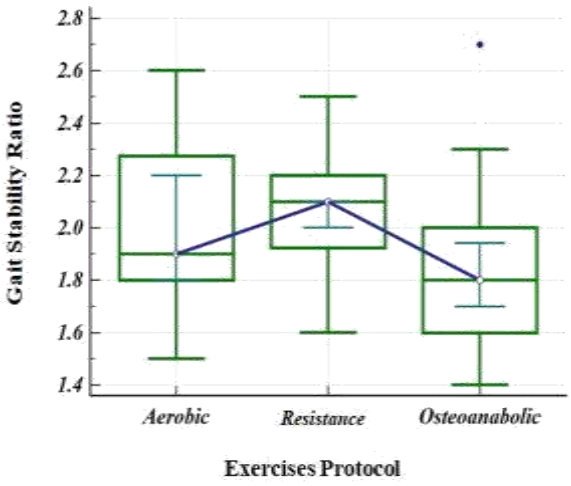

Figure 2 plot showing pre and post mean difference of GSR among aerobic, resistance and Osteoanabolic exercises training protocols

Paired t test was analyzed for pre and post analyses of Cadence, Gait velocity, TUG and FES-I. Pre and post Gait velocity mean difference was found to be highest among the osteoanabolic group (0.32±0.14) whereas minimum remarkable difference was observed in aerobic (0.16±0.14) and resistance group (0.15±0.077). Furthermore, the cadence mean±SD in aerobic group was 110.9±4.4; resistance group was 109.1±5.7 and Osteoanabolic group was 113.03±5.6. The TUG mean difference in aerobic group was -2.54±1.33, resistance group was -1.12±0.76 and Osteoanabolic group. In addition, FES-I mean difference in aerobic group was 9.5, resistance group was 6.3 and Osteoanabolic group was 15.38. However, pre-post analysis at 5% of alpha was found to be significant p<0.05 in all the three groups. (Table 1)

Table 1: Within the group analysis of all groups

Variable	Group A (Aerobic) n=31				Group B (Resistance) n=31				Group C (Osteoanabolic) n=31			
	Pre	Post	Dif	p-value	Pre	Post	Dif	P-value	Pre	Post	Dif	P-value
BMD*	2.6	2.3	0.3	<0.001	2.6	2.5	0.1	<0.001	2.6	2.2	0.4	<0.001
GSR *	2.2	1.9	0.3	<0.001	2.4	2.1	0.35	<0.001	2.3	1.8	0.55	<0.001
Gait Velocity**	0.78 ±0.1	0.94 ±0.12	0.16	<0.001	0.72 ±0.007	0.87 ±0.07	0.15	<0.001	0.74 ±0.08	1.06 ±0.16	0.32	<0.001
Cadence**	105.7 ±4.2	110.9 ±4.45	5.19	<0.05	106.4 ±5.13	109.1 ±5.756	2.67	<0.05	106.9 ±4.85	113.03 ±5.60	6.12	<0.05
TUG**	12.4 ±1.08	9.8 ±0.9	-2.54	<0.05	12.6 ±1.22	11.04 ±1.2	-1.12	<0.05	12.8 ±0.95	9.67 ±0.74	-3.16	<0.05
FES-I**	33.6 ±3.4	24 ±4.1	9.5	<0.05	37.5 ±2.8	31.2 ±3.9	6.3	<0.05	35 ±3.3	20.4 ±2.8	15.3 8	<0.05

* Wilcoxon Rangrd Test
**Paired t test

The difference in between the three groups using Kruskal Wallis test, BMD showed F-ratio of 28.59; p<0.05 suggest a significant difference between aerobic and resistance; F ratio 37.36; p<0.05 also suggest significant difference between resistance and Osteoanabolic whereas no significant P>0.05; F statistics 1.30 was observed between aerobic and Osteoanabolic. However GSR showed F-ratio of 2.2; p>0.05, a non-significant difference between aerobic and resistance, F ratio 1.89 p<0.05 suggestive of significant difference in resistance and Osteoanabolic Whereas P<0.05; F statistics 1.18 was observed between aerobic and Osteoanabolic favoring Osteoanabolic exercises over aerobic training in improving the GSR.

The Gait velocity and cadence showed a significant difference using one way analysis of variance ANOVA with a p-value <0.001. Further post hoc test showed the average rank of Osteoanabolic was significant p<0.05 at 95 % of CI followed by aerobic average rank. The TUG data revealed that F Ratio 31.93 between the 3 groups, found to be statistically significant with a p-value <0.001. Factor wise analysis reveals that a significant mean difference p<0.001 was found between aerobic and resistance group and Osteoanabolic and resistance group. However, no significant mean difference p>0.001 was found between aerobic and Osteoanabolic group. The FES-I F Ratio 67.98 between the 3 groups was found to be significantly different p<0.05. Factor wise analysis of FES-I reveals that a significant mean difference p<0.05 was found between all the groups.

Impact of exercises regimes on the future risk of fall where the baseline reading was found to be 33.6±3.4 in aerobic group was improved to 24±4.1 after 12 weeks of training. In anaerobic group the baseline reading was 37.5±2.8 was improved to 31.2±3.9 with a mean difference of 6.3, the maximum improvement was found in the Osteoanabolic group where the baseline readings were 35±3.3 was improved to 20.4 ± 2.8 with a mean improvement of 15.38. (Table 2)

The relative risk obtained shows that 30% reduction in the future risk of fall was observed in the Osteoanabolic group whereas 10% reduction was observed among the participants included in the aerobic training group. Whereas, the participants who were given intervention through resistance training group showed 10% increase in the future concerning risk of fall.

Table 2: shows the Relative Risk (RR) of exercise training strategies among the osteoporotic females

Intervention	RR	95% of CI	Observed	p-value
Aerobic	0.9	0.82 to 1.12	10 (+)	0.04
Resistance	1.1	1.002 to 1.31	10 (-)	0.04
Osteoanabolic	0.7	0.51 to 0.96	30 (+)	0.02

IV. DISCUSSION:

The finding of this study was based on four different outcomes. The Osteoanabolic exercise training protocol significantly improves the BMD, temporal-spatial parameters of gait, GSR, dynamic balance and FOF among the participants recruited in group C. All the training protocols were based on the guidelines provided by ACSM using the FITT protocol. The use of combination of training protocols, different stretching

and strength training exercises along with a sufficient warm up and cool down phases are found to be effective in improving these parameters. Moreover, the paradigm shifts from subjective measurement to objective measurement of approach has also been of keen interest to the author in this study.

The result of our study on BMD of participants depicts that exercises interventional regimes had a positive impact on T-score of the participants measured using a peripheral DXA scan. All the three training protocols were found to be significant where aerobic training protocol activates osteoblast in order to synthesize bone matrix and inhibit the bone resorption process whereas resistance training protocols enhanced the loading process reducing the bone resorption.

Literature has reported that different physical activity training programs are effective in improving the BMD These results were in accordance with the outcomes of Motorwala et al (19) where supervised yoga training was conducted on 30 women considering different asanas in different positions (standing, sitting, supine and prone). The training program consist of 1 hour yoga session for 4 days every week for 6 months where warm up, surya namaskars and Asanas were performed. As yoga, is a safe mode of physical activity including weight bearing and non-weight bearing asanas thereby improving BMD. Murtezani et al (20) introduced land based therapy, three resistive exercise session per week comprised of aerobic weight bearing, balance training and progressive resistance for a duration 10 months. An extremely comprehensive protocol that may be complicated for the patients were given causing strenuous impact on the age catered (50-70 years). Although resistance exercises were also given to our patients yet only dumbbells with 1 RM method was given to the osteoporotic females in order to make it tailored exercise training protocol.

It was further analyzed from various different researches that an increase in the muscle strength and with the involvement of one of the basic principles of training that is the principle of overload in order to improve the process of bones remodeling increases to multifold. However, Abrahin et al (21) concluded that the impacts of aerobic exercises particularly cycling and swimming had no positive outcome on the BMD of the participants. Similar results were observed by Kemper et al (22) and Mudd et al (23) Another study conducted by Silva et al 2011 (24), concluded that of all the different aerobic physical activity including swimming, soccer, and tennis; swimmers had the lowest femoral BMD in comparison to other sports activities, which further endorsed that only weight bearing exercises impact the skeletal system of human body that stimulates the process of local osteogenesis.

All three training groups were able to increase the cadence and gait velocity after the intervention of aerobic, resistance and Osteoanabolic group. The maximum increase was among the Osteoanabolic group with 6 days of training for twelve weeks. These results were inconsistent with the previous researches where it has been documented that the increase in the gait velocity more than 1 m/sec indicates an improvement in the functional status of the older adults (25-26). Although, aerobic training showed an improved mean difference of 0.16, results are found to be statistically significant ($p<0.05$) but no clinical significance is observed <1m/sec. In our study, we have used activPAL that is a research based accelerometer, requiring no calibration for gait velocity and cadence. It has been observed from a number of studies that quantifying the TSPs of gait is found to be a better indicator of gait when compared with other RBA like ActiGraph and wrist worn accelerometers.

As TUG was found to be successful in measuring the dynamic balance of the participants and it was revealed from our study that significant improvement was observed among the three groups. Our results in all three group were found to be consistent with that of Tomicki et al (27), Granacher et al (28), and Lee et al (29) where different training protocols such as core stability strength training program, aerobic endurance, muscle balance, motor coordination and virtual reality programs were performed. However, variability was observed in the duration of programs that ranged from 8 weeks to 12 weeks of training. Hess and Woollacott (30) concluded that 10 weeks of exercises based training protocol reduce the probability risk of falling from 50% to 20% similar to our study.

Previously, Dohrn et al (31) during a study reported that severe fear of fall and low fall self-efficacy has been a reason for self-restricted physical activity. Different balance single and dual task training programs has been documented among osteoporotic individuals showing an improvement in the fear of fall after training period of 12 weeks. Moreover, researchers raise a concern regarding increased FOF that has also been reported in our study at baseline and at 12^{th} week in the aerobic and resistance group i.e. 24±4.1 and 31.2±3.9 respectively. Our results of the resistance group were found to be consistent with multiple studies (32-34) where the control group was in the high level of concern. Therefore this FOF ultimately leads to activity limitation and participant restriction, therefore an exercise training program that increases the socialization of these individuals would be termed as beneficial.

V. LIMITATIONS OF THE STUDY:

This study was conducted in a single private hospital setting catering the upper middle class population only. This may affects the generalizability of research findings due to inability to compare findings accurately from one Centre to another. Moreover various studies have suggested that post-trial follow-up offers valuable evidence regarding long-term benefits and side-effects of the intervention. As there was no follow-up in this study therefore it lacks to determine the residual effects of the training protocol.

VI. CONCLUSION:

In this era of adjunct and alternative therapies, the concept of exercise as medicine emerged showing that specific structured and tailored exercise training protocols are effective in treating osteoporosis. Indeed, nearly all training protocols as were based on American College of Sports Medicine guidelines were effective in improving BMD, gait, balance and FOF among the females. The study also focused on relative risk of fall providing evidences for more follow up studies. Our study highlights the need of guidelines for the management of osteoporosis on national level with the higher prevalence being reported. However, due to the lack of national registries and paucity of data, Osteoporosis is yet not considered as a National Health

Problem with the sedentary life adopted by the females especially after menopause.

ACKNOWLEDGEMENT:
We are very thankful to all participants for taking out time, to complete this survey.

DECLARATION OF CONFLICTING INTEREST:
The author(s) declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

FUNDING:
The author(s) received no financial support for the research, authorship, and/or publication of this article. The study was completely self-funded by the researchers

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