

Risk Reduction Intervention for Osteoporosis and Osteoporotic Fracture among High-Risk People

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Abstract Introduction: Osteoporosis is a serious public health problem that currently causes global concern. Osteoporosis is a silent and potentially debilitating chronic illness that can cause fractures mostly in elderly. The National Osteoporosis Foundation (NOF; 2012) estimates that by 2025, osteoporosis will be the cause of 3 million fractures with an approximated healthcare expenditure of 25.3 billion dollars each year. In Egypt, the prevalence of osteoporosis in 2010 was 14.9% of the total population and it is projected to increase to 17.4% in 2020 and will further increase up to 30.3% by year 2050. **Aim:** to examine the effectiveness of risk reduction intervention for osteoporosis and osteoporotic fracture among high risk people. **Methods:** A quasi experimental design (study/control) was utilized. A convenience sample of Ninety subjects, who attended to the outpatient clinics, at Shebin El-Kom Menoufia University Hospital, Menuofia Governorate were selected. Data collection lasted six months from the beginning of September 2013 to May 2014. Tools: Fracture Risk Assessment Tool; Bone Mineral Density Test; General Practice Physical Activity Questionnaire, Calcium Food Calculator Questionnaire. **Results:** there was a statistical significant reduction of osteoporotic fracture risk score post intervention with mean score 5.16 ± 5.51 . In the study group, 48 % of the participants were classified as moderately inactive which reduced to 28% post intervention. Also, approximately a quarter (23 %) of participants in the study group was inactive pre intervention compared with 8% post intervention. There was statistically significant improvement in total calcium intake post intervention compared with pre intervention. **Conclusion:** The risk reduction intervention was effective in improving bone health as indicated by the significant improvement in BMD score and the improvement of the mean score of fracture risk post intervention. **Recommendations:** Nurses in the primary health care centers should provide education to their patients about the need for good bone health as well as how to conduct good bone health with adequate calcium and vitamin D intake and moderate exercise with weight-bearing activities. They should also take time to provide health promotion in respect to osteoporosis.

Keywords: osteoporosis, osteoporotic fracture, risk reduction intervention, high-risk people

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1. Introduction

Osteoporosis (OP) is a serious problem that causes global concern. Osteoporosis is a major cause of mortality, morbidity and medical expenditures worldwide [1]. Osteoporosis is a brittle bone disease that can cause fractures mostly in older people [2]. Globally, it is estimated that more than 200 million people have osteoporosis [3]. In Egypt, the prevalence of osteoporosis in 2010 was 14.9% of the total population and it is projected to increase to 17.4% in 2020 and will further increase up to 30.3% by the year 2050. In addition, 54% of postmenopausal Egyptian women have osteopenia while 28.4% have osteoporosis and 22 % of Egyptian males aged 20 - 89 years have osteoporosis [4].

Osteoporotic fracture (particularly, Osteoporotic hip fracture) can cause severe morbidity, mortality, disability,

or death. Approximately 40% of patients with an osteoporotic hip fracture never regain their pre fracture independence; 50% are independent incapacitated and 20% require long term care [5]. It is projected that the number of hip fractures secondary to osteoporosis will increase to 13 million in 2050. [6].

Osteoporotic fractures increase risk of mortality and morbidity and lead to considerable societal costs, including direct and indirect medical cost resulting from disability, and death [7]. Over 80% of all fractures in people of 50 years old and above are caused by osteoporosis [8].

Many factors that increase the risk of developing osteoporosis are modifiable risk factors such as: low activity level; people with a more sedentary lifestyle are more likely to have a hip fracture than those who are more active [9]. It is suggested that cigarette smoking inhibit the activity of osteoblasts and decrease Bone Mineral Density (BMD) [10]. Decrease consumption of calcium and

vitamin D cause increased production of parathyroid hormone (PTH). Excessive production of PTH led to increases of bone loss and low BMD [11]. Consumption of more than three cups of coffee daily might increase calcium excretion in the urine and affects bone health [12]. There is evidence that the risk of osteoporotic fractures can be controlled with risk reduction intervention includes diet, exercise, and preventing falls [13].

The escalating costs of osteoporotic fractures needs effective preventive strategies aimed at improving bone density and preventing bone loss. It is important for the nurses to have an insight about this problem to function at all levels of prevention to early identification of the problem prior to fracture occur [14]. Therefore, this study intended to shed light on the role of nurses on prevention of osteoporosis and osteoporotic fracture providing health education about healthy behaviors and avoiding the dangerous ones through increasing awareness about increase consumption of calcium, provide adequate intake of a diet rich in calcium, vitamin D, consuming nutrients with omega-3 fatty acids, and increase physical activity. Tailoring individualized intervention targeting people at risk of osteoporosis and osteoporotic fracture can reduce the risk and improve bone health. Thus, the purpose of this study was to examine the effectiveness of risk reduction intervention for osteoporosis and osteoporotic fracture among high risk people.

1.1. Aim of the Study

To examine the effectiveness of risk reduction intervention for osteoporosis and osteoporotic fracture among high risk people.

1.2. Research Hypotheses

1. Persons who will receive risk reduction intervention are more likely to have less risk to develop osteoporosis than those who does not receive the intervention.
2. Persons who will receive risk reduction intervention are more likely to have less risk to develop osteoporotic fracture than those who do not receive the intervention.
3. Persons who will receive risk reduction intervention are more likely to have a more physical activity level and improved bone mineral density than those who do not receive the intervention.

2. Methods

2.1. Design and Setting

A quasi experimental design (study/control) was utilized to examine the effect of using risk reduction intervention to reduce risk of osteoporosis and osteoporotic fracture. The study was conducted at the outpatient clinics in Menoufia University Hospital, at Shebin El-Kom City, Menuofia Governorate. The University Hospital was selected because of the considerable number of people at high-risk for osteoporosis attending to these outpatient clinics (1500) patients every month. Also, University

Hospital is a suitable place for giving health education to the participants.

2.2. Sample

A convenience sample of Ninety subjects, who attended to the outpatient clinics, at Shebin El-Kom Menoufia University Hospital, Menuofia Governorate were selected. These participants were approached over a Six month period from the beginning of September 2013 to May 2014. Eighty-five subjects consented to participate in the study. These subjects met the study inclusion criteria which included: a) ages from 40 to 65 years old, b) Had one or more risk factors for osteoporosis such as: low activity level; smokers; consume Caffeine and reported eating inadequate diets (low calcium intake and low vitamin D intake). Patients were excluded if they were: a) Using drugs such as: corticosteroid, thyroxin, anticonvulsants, anticoagulant and cytotoxic drugs, which may affect bone density; b) Having one or more chronic disease such as: Diabetes Mellitus, and Thyrotoxicosis, bone marrow disease (Leukemia and Multiple Myeloma), which may affect their bone; c) a history of osteoporosis or osteoporotic fracture; d) Pregnancy because pregnancy is associated with physiologic changes that affect all function of the body and requires more calcium and vitamins during pregnancy. Eighty participants completed the three follow-up measurement points. Among the five subjects who did not complete the follow-up measurements, three were excluded from the study because they are busy. Two subjects refused to complete the interview because they didn't have time. Eighty participants constitute the final sample.

Calculation of Sample Size: In order to calculate the required sample size, the researcher used the Epi statistical program from the Open Source Statistics for Public Health. The assumptions were: a two sided confidence level of 95% = $(1 - \alpha)$; a power $(1 - \beta)$ or (% chance of detecting) of 80%; ratio of sample size, unexposed (control)/ exposed (study group) = 1% of unexposed with outcome (awareness) = 5%; Then the researcher entered one of four parameters which was % of exposed, $s = 25\%$, and the others three parameters would be calculated by the Epi website program and results were presented using methods of Kelsey, Fleiss, and Fleiss (2010) [15] with a continuity correction.

2.3. Instruments

I) Semi-Structured demographic Questionnaire to collect data about age, marital status, educational level, monthly income, residency, occupation, and past obstetric history for women (e.g. age of menopause, number of children, and number of abortions); medication used and family history. Data were collected by the investigator at the initial data collection point. These variables were collected through face to face interview.

II) Fracture Risk Assessment Tool (FRAX): The FRAX was developed by the World Health Organization (WHO) task force in 2008 as a prediction tool for assessing an individual's risk of fracture and to estimate the probability of fracture in the next 10 years. Fracture risk of a patient was estimated based on the

following scores: Low < 10%, Moderate 10 - 20%, or High > 20% in the next 10 years, using known risk factors. Reliability of the total FRAX estimation was reported in a study of 3,850 women and 518 men age 50 years old and older at high risk of osteoporotic fracture by Leslie et al., (2010) [16]. Internal consistency was evaluated using Cronbach's alpha and it was 0.90 for the total scale. In the present study, test-retest reliability of the total FRAX was 0.87 at 8 patients with two weeks interval.

III) Dual X-ray Absorptiometry (DXA): The World Health Organization (2011) [17] has established DXA to measure bone mass as the best densitometry technique for assessing BMD. It was measured at 3 different sites: lumber (L1-L4), femur neck and ultra-distal end of the radius. The reliability of DXA was tested in a study of 459 patients for secondary prevention of osteoporosis by Barrack, et al., (2009) [18] in which the reported Cronbach's alpha was 0.87 for the total scale. In the present study, test-retest reliability of the total BMD was 0.84 at 8 patients with two weeks interval.

IV) General Practice Physical Activity Questionnaire (GPPAQ) [19]: GPPAQ used to measure activity of daily living. The scale consists of 8 questions answered by yes or no, to assess adult physical activity levels which included physical activity at home, work, and leisure time. The scores ranged from 0 (Inactive) to 10 (Active). The scoring system of the scale was interpreted in accordance with previous studies as follows: a simple 4-level Physical Activity Index (PAI) categorizing patients as: Active from 8 to 10, Moderately Active from 5 to 7, Moderately Inactive from 3 to 4, and Inactive less than 3. All patients who received a score less than Active were offered a brief intervention supporting behavior change to increase physical activity. Reliability of the GPPAQ was reported in adults 16 - 74 years old in routine general practice to provide a simple, 4-level Physical Activity Index (PAI) reflecting an individual's current physical activity by Pinto, et al., [20]. The reliability of GPPAQ was reported in a study of 83 patients aged 35-75 years, attending non-urgent consultations over two-week period to assess the acceptability of the GPPAQ to everyday general practice by Neil, [21] in which the Cronbach's alpha was 0.92 for the total scale. In the present study, test-retest reliability of the total GPPAQ was 0.87 at 8 patients with two weeks interval.

V) Calcium Food Calculator Questionnaire was developed by National Nutrient Database for Standard Reference, [22], and used for estimating daily dietary calcium intake from calcium-rich foods. It was used to find out: How much calcium is in certain foods? How much calcium was needed? How to add more calcium to the diet? Reliability of the calcium food calculator questionnaire was estimated using reported calcium food intake of 102 women over age of 50 years. The osteoporosis knowledge and health beliefs were assessed using preventive health habits such as adequate calcium intake and physical activity by using the calcium food calculator questionnaire by Siris, et al., [23]. Internal consistency was evaluated using Cronbach's alpha and was approximately 85% for the total questionnaire. In the present study, test-retest reliability of the total Calcium food calculator questionnaire was 0.84 at eight patients with two weeks interval.

VI) Body Mass Index was calculated based on the following formula, body mass index (BMI) = Weight (kg) / Height (m) ² [24], BMI Categorized as Underweight = <18.5, normal weight = 18.5-24.9, overweight = 25-29.9, obesity = BMI of 30 or greater and measured in all patients in the initial visit and follow up visits.

VII) Dietary History and Special Habits Questionnaire: Dietary history included calcium and vitamins intake (milk and dairy products). Special habits included caffeine consumption (coffee, tea and cola drinks) sun exposure and smoking were collected.

2.4. Ethical Consideration

An official permission for conducting the study was obtained from the Faculty of Nursing and Menoufia University Hospital directors. A written consent was obtained from subjects. The investigator explained the purpose and procedures of the study to the subjects. Confidentiality of all information was warranty. Subjects were assured that their participation in the study is voluntary and that they can withdraw from the study at any time. They were informed that participation in the study has no cost and they can benefit from the free tests offered to them.

2.5. Pilot Study

A Pilot study was conducted to test the readability of the questionnaires It also helped to estimate the time needed to complete the questionnaires. It was conducted on 8 participants whom were excluded from the final analysis.

2.6. Data Collection Procedure

Individuals who met the study inclusion criteria were interviewed by the investigator and data was collected using the prepared questionnaires. Eighty adult with one or more risk factors of osteoporosis were randomly assigned into two equal groups (40 participants each). The random assignment of the participants to either study or control group took place by writing all names of the participants in slips of paper, placed in container, mixed well, and then drawn out one at a time and alternatively placed in one of the groups until assigning the required number of participants completed.

The Initial Visit (Pre intervention)

The first time the researcher met the participants was considered the baseline measure. Participants were interviewed in the outpatient clinic to complete the study questionnaires which included: Demographic Questionnaire; Fracture Risk Assessment Tool (FRAX); Dual X-ray Absorptiometry (DXA); General Practice Physical Activity Questionnaire (GPPAQ); Calcium Food Calculator Questionnaire; BMI and Dietary History and Special Habits Questionnaire.

Study Group (Initial Visit): Participants in the study group were given health education about risk reduction intervention that included oral presentation with open discussion supported by an educational information booklet. The session took 25- 30 minutes. In addition, they were informed about the intervention objectives,

contents and its benefits. The intervention consisted of three components:

- I) **Dietary Education:** The objective was to maintain a healthy diet and to discuss daily recommended intake of calcium and vitamin D, increase awareness and knowledge about good nutritional practices; type of food and drinks that are rich in calcium such as skimmed, low-fat and whole milk; low-fat plain yogurt and daily calcium required (Adults 19 years and older 700 mg per day). Also, the researcher discussed with participants the important sources of vitamin D and exposure to sunlight to help absorption of calcium and vitamin D.
- II) **Physical Activities:** Each participant in the study group was instructed to follow the simple walking program, which include walking 10 minutes in open air 4-5 times/week [25]. The duration increased gradually by 5 minutes every week until it reaches 45 minutes. Also, having at least 150 min/week of moderate-intensity aerobic physical activity (i.e., brisk walking) (or 10,000 steps) at least 5 days per week. The walking program with some other simple exercise which can be done at home for osteoporosis prevention was explained. Participants were instructed to have rest periods of 2 minutes when they feel tired. Also, the researcher instructed participants about various kinds of exercise, particularly load-bearing exercises that induce an increase in BMD and may indirectly protect individuals from fractures by improving mobility, muscle strength and balance.

- III) **Education about unhealthy habits practices** that should be avoided such as excess salt intake, excessive caffeine consumption, smoking that increases bone loss. The instruction was developed to give the same knowledge for every participant in the control group.

Final visit (Post intervention)

The researcher interviewed the participants again after 6 months at the end of the intervention and re-administered the study questionnaires and repeated DXA scan to assess the level of improvement and how the intervention improved the BMD and the change in the fracture risk score.

Control Group: Participants in the control group were exposed to routine hospital care which includes different medication prescribed by their treating physician.

3. Results

3.1. Characteristics of the Study Sample:

Ninety patients were approached over a 6-month period. Eighty-five persons consented to participate in the study. Eighty participants completed the planned six follow-up measurement points. Three out of the five participants who did not complete the planned follow-up measurement, were excluded from the study because they were taken corticosteroid medication. Two participants refused to complete the interview because they didn't have time. The final sample consisted of eighty subjects.

Table 1. Socio-demographic Characteristics of the Study Sample

Demographic Variables	Study Group (n = 40)		Control Group (n= 40)		χ^2	P
	NO	%	NO	%		
Age						
• 40-	18	45	18	45	1.7	0.43
• 50-	17	42.5	13	32.5		
• 60-65	5	12.5	9	22.5		
• X ± SD	49.9 ± 7.1		51.2 ± 7.1			
Sex						
Male	20	50.0	20	50.0	0.09	1.0
Female	20	50.0	20	50.0		
Marital Status						
Single	1	2.5	1	2.5	LR=0.07	1.0
Married	37	92.5	37	92.5		
Widow & Divorced	2	5.0	2	5.0		
Level of Education						
Illiterate and R & W	6	15.0	10	25.0	LR= 8.9	0.08
Primary	2	5.0	6	15.0		
Secondary	20	50.0	21	52.5		
University	12	30.0	3	7.5		
Occupation						
Employee	74	75	72	80	LR= 11.3	0.06
Not Employee	6	15	8	20		
Residency						
Rural	30	75	20	50	5.3	0.07
Urban	10	25	20	50		
Monthly Income						
Less than enough	18	45	23	57.5	LR= 6.6	0.08
Enough	22	55	14	35		
More than enough	0	0	3	7.5		

The mean age of participants in the study group was 49.9 ± 7.1 where in the control group was 51.2 ± 7.1 . The majority of participants in both study and control group were married (92.5% and 92.5% respectively). Half of the participants in both study and control group have secondary education (50.0% and 52.5% respectively). More than two thirds of the participants in both study and control group were employees (75% and 80% respectively). According to family medical history, approximately less than half of the participants in both study and control group had family history of osteoporosis (45.7% and 43.3% respectively).

Figure 1 shows that approximately third of the participants in both study and control group were overweight (35% and 33% respectively). Approximately 10% of the studied sample had normal BMI and only 2.5% of the control group were underweight (BMI<18.5).

The study hypothesized that the persons who will receive risk reduction intervention are more likely to have less risk to develop osteoporotic fracture than those who do not receive the intervention. The mean score of FRAX in the study group was 5.16 ± 5.51 after intervention while for the control group it was 8.09 ± 7.33 . Thirty Five percent of the participants in the study group had no risk of fracture in the next ten years and this percent increased to 45 % post intervention and 23 % had moderate risk of fracture post intervention reduced to 8 % compared with pre intervention. Also, approximately 12% had marked risk of fracture reduced to 10% post intervention. See Figure 2.

The study hypothesized that persons who will receive risk reduction intervention are more likely to have increased physical activity level and improved Bone Mineral Density (BMD) than those who do not receive the intervention. See Figure 3 and Figure 4.

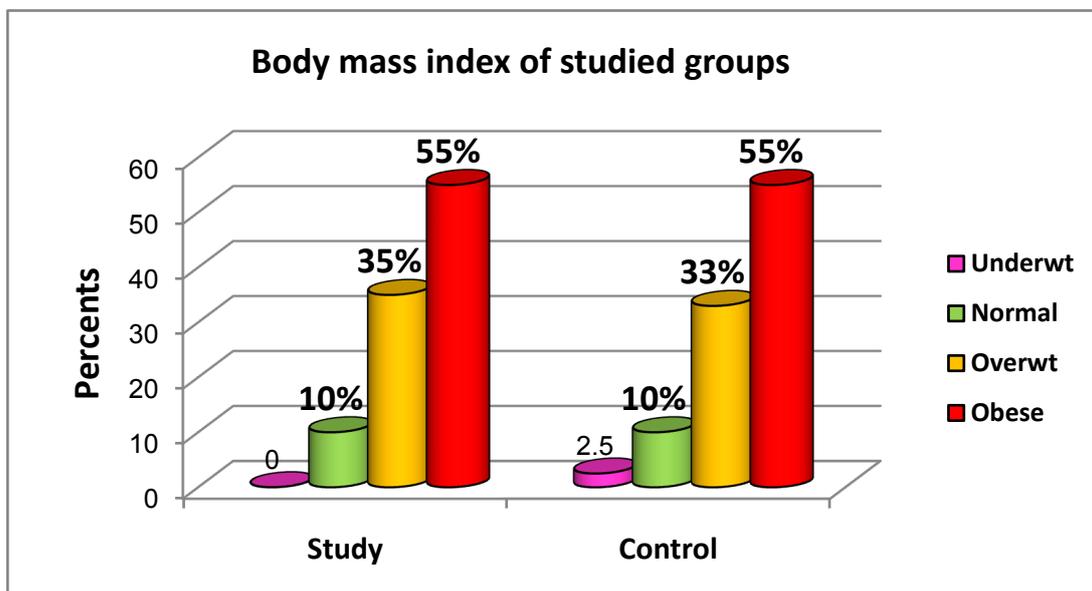


Figure 1. Frequency Distribution of the Body Mass Index of Study and Control Group

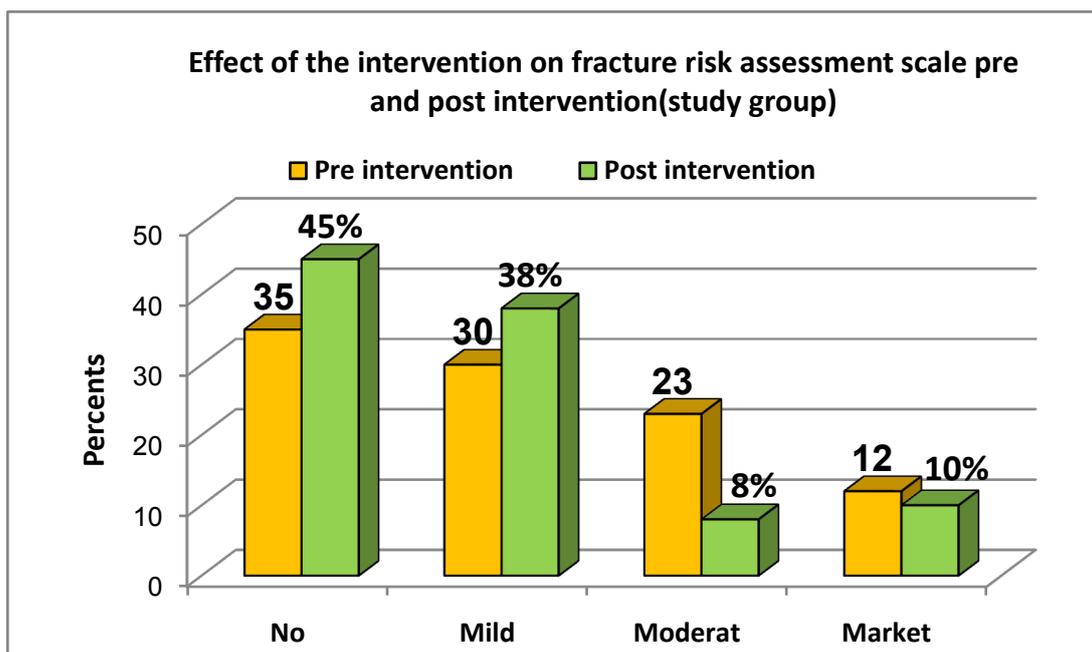


Figure 2. Effect of the risk reduction intervention on fracture risk assessment scores post intervention

Table 2 shows that there was statistically significant improvement in total calcium intake post intervention compared with pre intervention.

4. Discussion

The present study hypothesized that persons who receive risk reduction intervention are more likely to have less risk to develop osteoporosis than those who will not receive the intervention. The findings of the present study revealed that there was a highly statistically significant improvement in the mean scores of BMD on femur neck and radius bone post intervention compared with pre intervention. Additionally, there was a statistically significant improvement in the BMD on lumbar spine post intervention compared with pre intervention in the study group. The findings of the present study are similar to what was reported by Jeihooni et al., [26] who studied the effects of an educational program on preventing osteoporosis in Iranian woman for six months and found a statistically significant improvement in the BMD post intervention.

Also, the findings of the present study were similar to Bechtel [27] who studied the effect of osteoporosis risk reduction intervention on bone health in Iraq and found a statistically significant improvement in the BMD and bone health after intervention among the study group compared with the control group. Similar findings were reported by Moschonis et al., [28] who studied the effects of a 30-month of risk reduction intervention on BMD and found statistically significant improvement in the mean scores of the DXA score after intervention including femur and radius bone than before the intervention.

However, the findings of the present study are different from what was reported by Xu, et al., [29], who studied the effect of an intervention program on prevention of osteoporosis in Italy and found no beneficial effect on bone health and BMD over the 3-months intervention. These findings could be related to the short duration of the intervention. Also, the current study findings are different from what was reported by Zibellini et al., [30], who examined the effect of dietary intervention on improving BMD and decreasing bone loss among London obese adult for 24 months and found no statistically significant improvement in the total score of BMD post intervention. A possible explanation of the study findings might be that the intervention focused only on dietary management and excluded other dimensions of management such as exercise and maintenance of a healthy lifestyle.

4.1. Effect of Risk Reduction Intervention on Fracture Risk Score

The present study hypothesized that persons who receive risk reduction intervention are more likely to have less risk to develop osteoporotic fracture than those who will not receive the intervention. The findings of the present study revealed that, there was a statistically significant decrease in the fracture risk score in the next ten year among the study group post intervention compared with the control group. Also, there was a significant reduction of FRAX in the study group post intervention compared with pre intervention. Moreover,

findings of the present study show that 12.5% of the study group was at high risk of fracture in the next ten year pre intervention and this percent decreased to 10% post intervention. Also, more than 22.5% of the study group had moderate risk of fracture in the next ten year pre intervention decreased to 7.5% post intervention.

The findings of the study are similar to Chao, et al., [31] who studied the effect of using the Fracture Risk Assessment Tool (FRAX) in identifying post menopausal women at risk of osteoporotic fracture and how can intervention reduce the osteoporotic risk and found that 26% of women were classified as having intermediate risk and 37% were classified as having high risk for osteoporotic fracture. Also, there was a statistical improvement of BMD and reduction of fracture risk in the study group post intervention compared with pre intervention. In addition, the present study findings are similar to Closkey, et al., [32] findings whom studied the effect of risk reduction intervention of osteoporotic fractures in post menopausal Italy women with moderate to high fracture risk and found that the risk of osteoporotic fractures decreased post intervention compared with pre intervention. Also, the intervention led to a 32% reduction in osteoporotic fractures.

However, findings of the present study are different from what was reported by Capri [33] who examined the effect of intervention on preventing bone fractures after menopause for 28 weeks in the USA and found that there were no statistical significant differences of fracture risk score post intervention compared with pre intervention. The discrepancy in the findings between the two studies can be explained by the fact that in Capri study the intervention focused on calcium supplement and exercise, whereas, in the current study the intervention was more comprehensive and included more preventive measures.

4.2. Effect of Physical Activity on Osteoporosis Risk Reduction

The present study hypothesized that persons who receive risk reduction intervention are more likely to have increased physical activity level and improve BMD than those who will not receive the intervention. The finding of the present study revealed that there was a statistically significant improvement in the mean scores of physical activity level post intervention compared with pre intervention. The findings of the present study are similar to what was reported by Winkelmann et al., [34] who studied the effect of physiotherapy and exercise therapy for prevention of osteoporosis for 6 months and found that exercise and regular walking were associated with a statistical significant increase in BMD post intervention. Also, findings of the current study are similar to the findings of Babatunde and Forsyth [35] who studied the effect of lifestyle exercise on bone health of premenopausal American women and found that high impact exercise may be a potential public health prescription for enhancing pre-menopausal bone-health. However, findings of the present study are different from what was reported by Todd, and Robinson, [36], who studied the effect of exercise and activity on bone mass in postmenopausal German women, and found that there were no significant differences between the two groups

over the 1-year follow-up for any of the outcome measures. These findings could be explained by the fact that the sample was elderly patients with low BMD, who are already at risk of osteoporosis and osteoporotic fracture due to the degenerative process of aging.

5. Limitations of the Study

1. The results of study are limited in their generalizability because of the convenience sample. The lack of random sampling may contribute to sample selection bias and limit generalization of the findings.
2. Other limitations relate to the small sample size, using a single setting for data collection and the short period of the study (6 months) which was very short to show significant changes in bone health.

6. Conclusion and Recommendations

The risk reduction intervention was effective in improving bone health as indicated by the significant improvement in BMD score and the improvement of the mean score of fracture risk post intervention. Also, findings of the current study showed that there was an increase in participants physical activity level, increased total calcium intake and change lifestyle in certain special habits such as reducing consumption of caffeine, increasing exposure to sunshine, and eating a healthy diet rich in calcium and vitamin D.

Preventing osteoporosis using non-pharmacologic methods is a primary goal in maintaining bone health. Nurses need to be informed and encouraging about the use of non-pharmacological measures to assist the patient at risk for osteoporotic fractures.

Nurses in the primary health care centers should provide education to their patients about the need for good bone health as well as how to conduct good bone health with adequate calcium and vitamin D intake and moderate exercise. Community health nurses should provide health promotion regarding osteoporosis.

Expanding the educational programs on larger scales in schools and universities on the nutritional benefits of calcium and Vitamin D intake would be beneficial.

Lifelong physical activity is strongly recommended for the prevention of osteoporosis (National Osteoporosis Foundation). A modest increase in bone density may occur with exercise. Thus, education on the necessity for moderate exercise with balanced diets can improve bone health.

The study period should be extended more than six months. Extending the follow-up period will provide more comprehensive information about the effect of osteoporosis and osteoporotic fracture risk reduction interventions.

Replication of this study is recommended with several design changes such as, the use of randomized selection to achieve appropriate representation of the population, using a large sample size and including multiple centers.

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