ORIGINAL ARTICLE

A randomized field trial for the primary prevention of osteoporosis among adolescent females: Comparison of two methods, mother centered and daughter centered

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Background: Osteoporosis is a serious public health. Since the majority of bone mass occurs during adolescence, primary prevention is important. Probably mother's participation in health education interventions leads to promote health behaviors in children. **Aims:** To assess a lifestyle modification intervention focused on mothers and students has an impact on osteoporosis preventive behaviors in adolescent girls. **Materials and Methods:** It is a randomized field trial in female high schools. 210 girls aged between 11 and 15 were randomly selected. Students in groups A and C and mothers in group B were selected Through the sampling frame. Our lifestyle modification was based on group based education in the public girls' high schools. Subjects in the intervention groups participated in three educational sessions. Students' osteoporosis preventive behaviors were measured by using a lifestyle questionnaire consisting of items assessing nutrition, physical activity and sun exposure. Repeated measure ANOVA at baseline, 4 week, 2 months and 6 months and were used to analyze the data. **Results:** After 1 month, diet and sun exposure scores increased significantly ($P < 0.001$) but it was higher in group B compared with group A. (About diet $P < 0.001$ and sun exposure = 0. 001). After 6 months, diet and sun exposure status in the group A approximately decreased to baseline, while in group B, diet components were significantly different compared to baseline ($P < 0.001$). There was no change in physical activity. **Conclusion:** Osteoporosis prevention intervention of adolescent can be effective when parents or girls participate in training sessions, but education is associated with better outcomes when focused on mothers.

Key words: Community intervention, daughter centered, lifestyle, mother centered, osteoporosis, primary prevention

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INTRODUCTION

Osteoporosis, a major public health threat, influences more than 25 millions of Americans.[1] According to the report of the Research Center for Endocrinology and Metabolism of the Tehran University, 70% of women and 50% of men over 50 years old are living with osteoporosis or osteopenia.[2,3] Most people are unaware that they have osteoporosis until a fracture happens, because usually they do not have any signs or symptoms. Bone mass density is critical for strong bones. Since over 40% of bone mass in the adult is established during adolescence thus increasing of it through these years may be an important issue that will prevent osteoporotic fractures during later life.[4-6]

Many risk factors for osteoporosis has been noted, such as age, sex, genetic, race and body structure that is not changeable, but preventive life style behaviors such as a balanced diet , physical activity and also avoiding risk factors such as smoking, salt, cola-type beverages and caffeine should begin at childhood and adolescence. These choices play a significant role in the attainment of picking bone mass. Nof 2013.[5,7] Several studies have estimated that 20-50% of the variation in bone density is affected by lifestyle.[8] Enough dietary calcium consumption, regular weight-bearing physical activity, adequate consumption of Vitamin D make the most of peak bone mass during this period of time.[9-11] Vitamin D is the main factor, because it helps body to absorb the calcium in the diet and Sunlight exposure is a strong source of vitamin D. Nof 2013.[10,12,13]

Health education on osteoporosis is critical for adolescent to be aware of the causes and symptoms of osteoporosis and give the critical long-term effects of this illness for

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them.[14] In Addition , mothers involvement in children's education can be useful.[15] Previous interventions have shown the Advantages of parental support for developing children's dietary behaviors.[4] Since parents can provide a well contextual setting for their children, it seems that they can have an important role in interventions targeted at preventing or treating weight-related problems.[16] Interventions that have focused parental engagement (as well as regulation and problem solving) have been effective in reducing undesirable behavior in the future.[17] Training mothers about nutrition, led to increasing uptake of calcium and Vitamin D in their children.[18]

The first stage of our study indicated that most of the girl teenagers in Isfahan, Iran did not have a protective lifestyle, and it is necessary to develop an effective intervention to improve their lifestyle. The aim of this study was an assessment of mothers and students focus lifestyle modification intervention on behavior changes in relation to osteoporosis prevention of 12-15-year-old students girls in Isfahan Iran.

MATERIALS AND METHODS

This study was a multi-center, randomized field trial to compare the effectiveness of the two methods (Mother centered and Daughter centered) in a 3 week lifestyle modification intervention on improvement of dietary status, physical activity level and the use of sunlight. The investigation was approved by The Medical Ethics Committee of Isfahan University of Medical Science.

This is the second phase of the field trial, which had been carried out in three all- female High Schools between September 2013 and February 2014 in Isfahan, Iran. The sample size of the trial was estimated 210 participants (70/group) after consideration 10% attrition rate to increase the power of the study (power = 80% with type I error = 0.05, standard deviation [SD] = 20). Each subject gave informed consent before participating in the intervention.

Sampling was conducted in three stages. The First one includes a list containing all 120 public female high schools in Isfahan province, was prepared by the Department of Training and Education then within the sampling frame of six urban education and training regions, three schools were selected by simple random sampling. To prevent contamination, the groups were selected from different schools the schools were classified into three groups based on randomized allocation. After coordination with managers, the first school was selected for education of girls (daughter centered = group A), the next selected for education of the mothers (Mother centered = group B) and the last one, was selected as a control group (group C). All three schools have had a health educator. The next step was to select students in both groups A and C. Through the sampling frame 70 students were selected. The sampling flow was about the official number in each grade. They were asked to take participate at the specified time in the meeting. Furthermore, in group B 70 mothers randomly selected from the list of the parents. They were invited by letter to participate in training sessions that is about healthy lifestyles in order to prevent osteoporosis in their daughters. They got a package including a letter from the head researcher, detailed information about research aims, a timetable, and consent form.

Inclusion criteria

Healthy female students aged between 12 and 15 who were studying in one of the selected schools during the period of the research and who were interested in the participation as well.

Exclusion criteria

Specific disease or use of medication during the study that may influence the absorption or excretion of calcium, unwillingness to participate in the study, any questionnaire that was not filled >20%, any subjects who would not participate at least once.

Questionnaire

The instrument for gathering information was a multicomponent lifestyle questionnaire concerning behaviors that prevent osteoporosis. The questionnaire consisted of two parts and 35 questions: The first part included demographic information and the second part contained different aspects of life related to osteoporosis prevention including: Food frequency, sun exposure and, physical activity the girls indicated the times per day or per week they ate a food or beverage or specified if they did not consume the certain food. They specified items regarding their sun exposure quality and quantity they were asked about daily and weekly physical activity. The range of lifestyle score based on diet and sun exposure were 0-172 points (139 poins belonged to The diet and 33 points about sun exposure) that categorized to three levels, undesirable: Rating from 0 to 86 (below 50%), semi-desirable: 87-144 (between 50% and 84%) and desirable: More than 145 (between 85% and 100%). About the exercise, 400-1000 (min/week) was considered to be desirable score and other scores were undesirable.

Validity and reliability of the questionnaire was developed by Rahnavard *et al*. (Cronbach's alpha = 0.77).[19] All girls in the three groups complete this questionnaire 4 times in order to follow up: At the beginning of the study before the first session, 4 weeks after the baseline, 2 months after the 0 and repeated after 6 months for long term follow-up. All of the groups were similar in follow-up.

Content of the intervention program

Our lifestyle modification was based on group based education in the public girls' high schools. We had created an easily understandable educational booklet for adolescents 12-15 years. The intervention training package included the following topics: Epidemiology and complications of osteoporosis, risk factors, behavioral choice that prevents osteoporosis, exercise, diet and the benefits of using sunlight. In addition to written materials a video CD, a documentary movie about osteoporosis prevention, was prepared which was exhibited during the course. It was prepared by the Research Center for Endocrinology and Metabolism of the Tehran University.

The intervention program consisted of three meetings each week. Each was approximately 90 min. Health trainer teachers who worked in these schools were trained about lifestyle modification package by the researcher. They handled the meeting all of the participants groups A and B received one educational package in the second meeting. The content of the meeting of the two groups was similar.

Data analyses

We measured all data 4 times (repeated measure, baseline, 4 weeks after the intervention, 2 months and 6 months). All analyses performed by using SPSS version 20. (SPSS Inc., Chicago, IL, USA). Chi-squared analysis used to explore associations between qualitative data. We used *t*-tests and repeated measures ANOVA analysis. Data analyzed based on intention-to-treat basis, the level of significance established for a two-tailed *t*-test was 0.05.

RESULT

Of the 210 participants, 195 subjects participated in the study. 66 subjects in group A, 60 in group B and 69 persons in the control group attended in our intervention and completed the questionnaire before, 4 weeks, 2 and 6 months after the intervention. The response rate was 92.8% [Figure 1]. During the intervention all of the subjects responded to all of the questions because of the close investigator's follow-up.

Table 1 presents participants' demographic characteristics subject's age ranged from 11 to 15 years old with the mean of 13.18 ± 0.77 years. There were no statistically significant differences in demographic variables including: Financial status family member numbers Birth rank body mass index father and mother's educational level between three groups. For controlling possible confounders, we entered demographic data in the model (repeated measures analysis), but it wasn't statistically significant.

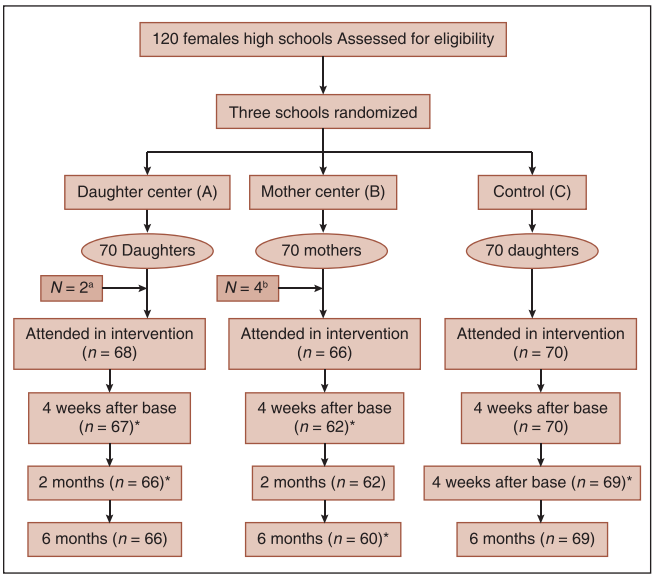

Figure 1: Flow of subjects through the trial. (a) Subjects were excluded. one of which consume ANTI ACID and one levothyroxine Na, (b) subjects were excluded two of which consume ANTI ACID, one suffered from severe asthma requiring steroid treatment, one suffered from Type 1 diabetes mellitus (*subjects refused to participate)

Table 1: Participants' demographic characteristics

Demographic variable	Mother center (B) *n* = 60 (%)	Doughter center (A) *n* = 66 (%)	Control (C) *n* = 69 (%)	*P*
Mean age (SD)	13.08±0.73	13.25±0.72	13.18±0.86	0.47
Weight	47.09±8.83	46.58±8.90	47.08±9.15	0.74
Height	156±0.74	157±0.75	156±0.80	0.65
Father education				
Illiterate	1 (1.7)	1 (1.5)	0 (0)	0.20
Primary school	9 (15)	4 (6.2)	4 (6)	
Under high	9 (15)	16 (24.6)	8 (11.9)	
School	28 (46.7)	26 (40)	39 (58.2)	
Diploma university	13 (21.7)	18 (38.3)	16 (34)	
Mother education				
Illiterate	1 (1.7)	0 (0)	0 (0)	0.21
Primary school	5 (8.3)	4 (6.1)	3 (4.4)	
Under high	16 (26.7)	9 (13.6)	8 (11.8)	
School	26 (43.3)	41 (62.1)	41 (60.3)	
Diploma university	12 (20)	12 (18.2)	16 (23.5)	
Financial status				
Poor	3 (5.2)	3 (4.5)	0 (0)	0.24
Fair	15 (25.9)	16 (24.2)	10 (15.6)	
Good	38 (65.5)	43 (65.2)	47 (73.4)	
Excellent	2 (3.4)	4 (6.1)	7 (10.9)	

SD = Standard deviation

The average consumption of foods (time/day) were assessed by questionnaire. At baseline regarding the diet In group

A, 16.7% (N = 11) of the girls had undesirable and 83.3% (N = 55) had semi desirable lifestyle, while 8.3% (N = 5) were categorized at undesirable and 91.7% (N = 55) at semi desirable classification in group B. 21.1% (N = 14) had undesirable and 78.8 % (N = 52) did semi desirable lifestyle in control group. No subject had desirable diet condition. There was no significant difference between three groups' diet at baseline (P = 0.75).

Table 2 for the mean percentage of desirability of diet (MPDD) and SD in groups for each time point. The group B had significantly high desirable diet condition at 4 week after the intervention (67.79%) compared to the daughter centered group. (58.74%). Both of them had a significant rise regarding the desirability of diet compared to baseline (P < 0.001). After 2 months MPDD of group B had significantly decreased about 7% compared to 4 week (P < 0.001). However, we did not find statistically significant decrease in group A. The MPDD 2 months after compared to the baseline in this group was significant (P = 0.004). Six months after the intervention the MPDD in group B (60.06) did not reach to the baseline value. There was no significant difference between the last measure and baseline in group A. Based on repeated measure ANOVA test MPDD from baseline to 6 months follow-up for the control group did not change significantly over the time. Regarding the milk consumption at the 0 time 16 subject (8.2%) did not drink at all, and 18 (9.3%) ate >2 times/day, while after sessions these rate were 13 (6.7%) and 22 (11.2%) respectively. There is statistically significant (P < 0.001) only in group B. Fifteen participants (7.7%) added and 104 (53.3%) did not add salt on the table at the baseline, while 13 (6.7%) participants added and 108 (55.4%) did not add after the intervention.

The intervention on sun exposure quality and quantity showed that, the group B had significantly higher at 4 weeks after compare to the group A (P < 0.001). Increasing in the mean percentage of desirability of sun exposure in this group was statistically significant too (P < 0.001). The scale of sun exposure fell approximately 11% in B and 7% in group A after 2 months but still significantly different from the base (P = 0.009 and P

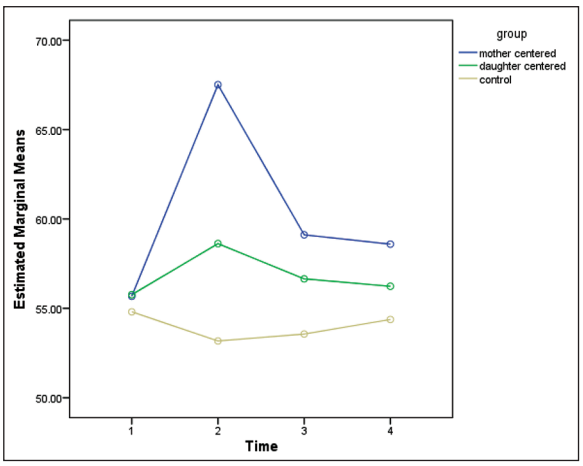

Figure 2: Mean percentage of lifestyle (diet &sun exposure) in baseline and fallow up times

Table 2: Mean percentage, SD and *P* value of desirability of diet (MPDD) in groups for each time point

Time	Group						*P*
	Mother centered (B)		Daughter centered (A)		Control (C)		
	Mean (%)	SD	Mean (%)	SD	Mean (%)	SD	
Baseline	56.59[a]	5.40	56.94	6.72	56.13	6.33	0.75
4 weeks after the intervention	67.79[b]	3.69	58.74	5.62	55.42	7.67	<0.001
2 months	60.29[c]	4.91	57.88	5.99	55.82	8.26	<0.001
6 months	60.06[d]	4.26	57.50	5.35	55.96	7.36	<0.001
P	<0.001		<0.001		0.393		

SD = Standard deviation; MPDD = Mean percentage of desirability of diet; a: P<0.001; mean percentage of desirability of diet (comparing mother Baseline vs. 1 week); P<0.001; (comparing mother Baseline vs. 2 month); P<0.001; (comparing mother Baseline vs. 4 month); b: P<0.001; (comparing mother 1 week vs. 2 month); P<0.001; (comparing mother 1 week vs. 4 month); P<0.001; (comparing mother center vs. doughter center); P<0.001; (comparing mother center vs. control group); c: P=0.04; (comparing mother center vs. doughter center); P<0.001; (comparing mother center vs. control group); d: P=0.016; (comparing mother center vs. doughter center); P<0.001; (comparing mother center vs. control group)

Table 3: Mean percentage, SD and *P* value of desirability of sun exposure in groups for each time point

Time	Group						*P*
	Mother centered (B)		Daughter centered (A)		Control (C)		
	Mean (%)	SD	Mean (%)	SD	Mean (%)	SD	
Baseline	50.99[a]	11.52	49.18	10.66	47.65	11.46	0.251
4 weeks after the intervention	64.80[b]	12.28	57.52	12.99	46.46	11.84	<0.001
2 months	53.47[c]	11.74	50.32	10.66	46.11	11.89	0.001
6 months	52.33[d]	10.37	49.81	8.84	47.56	9.44	0.02
P	<0.001		<0.001		0.313		

SD = Standard deviation; a: P<0.001; mean percentage of desirablity of sun exposur (comparing mother Baseline vs.1 week); P=0.01; (comparing mother Baseline vs.2 month); b: P<0.001; (comparing mother 1 week vs. 2 month); P<0.001; (comparing mother 1 week vs. 4 month); P=0.001; (comparing mother center vs. doughter center); P<0.001; (comparing mother center vs. control group); P<0.001; (comparing doughter center vs. control group); c: P<0.001; (comparing mother center vs. control group); P=0.03; (comparing doughter center vs. control group); d: P=0.005; (comparing mother center vs. control group)

< 0.001 respectively). In the last time, both of the intervention groups declined as much as the baseline [Table 3 indicates mean percentage, SD and *P*-value of desirability of sun exposure in groups during the follow-up of, 4 week 2 month and 6 month of the study]. Before study 53 (27.3%) subjects were exposed to the sun, ½-1 h. This was after intervention 87 (44.6%). The significance level of this item between base and 4 weeks, was 0.025 in mother group. Figure 2 shows the mean percentage of life tyle (diet and sun exposure) in baseline and fallow up times.

Table 4 shows the results of exercise in three groups. 47.7% of these girls exercised <30 min/week outside the school. There were no significant differences between short and long term follow up in all groups.

DISCUSSION

This study was handled out to evaluate effects of different types of lifestyle modification intervention on adoption of preventive behaviors. The results illustrate the fact that, an educational intervention for primary prevention of osteoporosis in adolescent might be improve girl's diet and sun exposure, regard that whom is educated, mothers or teenagers. Giving information about the importance of osteoporosis give us enough insight to adopt a healthy lifestyle. Health education is effective to prevent diseases that are related to lifestyle. Results of the studies provided evidences that osteoporosis prevention education was effective for a change in behavior, and this should begin in adolescence and continue throughout adulthood.[20-22]

As a fact, lifestyle wasn't desirable regarding the nutrition exercise and sun exposure in the studied subjects. On the other hand, the majority of them had semi desirable diet condition; no subject had desirable condition in this respect regarding the exercise 64.4% of the participants did not have an acceptable lifestyle, and 35.6% had a desirable lifestyle. Regular daily sun exposure quality and quantity was not favorable in most of the studied subjects. The findings of the other studies consistent with our pretest findings. In Rahnavard *et al.* study the most of the female teenagers did not have a desirable condition regarding the nutrition and exercise.[19] Kristal study revealed that 25% of female adolescents were smokers, 58% consumed calcium less inadequately, and 52% had low to moderate physical activity levels.[23] in Yekefallah *et al*. study 66.7% female adolescents and 34.7% of male adolescents used diet Including Vitamin D, cola-type drinks and caffeine. Approximately, 33.5% of the boys and 26.9% of the girls drank one cup of milk per day. Furthermore, only 9% of male students and 6.7% of female students were exposed to sunlight.[24]

After the intervention, students in mothers and daughters groups showed significant improvement in relation to the diet. The increase in the mean percentage point of the diet in Mothers group was 11, while this was 1.8 in daughters. These values gradually decreased in both groups, after 6 months, although in the daughters group approximately equal to the basic level, in mothers it was still 3.47% higher than the baseline. Winzenberg study on 345 mothers, demonstrated that parental education on nutrition and Vitamin D, led to an increase in calcium intake in children by 47%. According to this study: "Change in calcium supplement use alone perhaps demonstrates some motivation to change osteoporosis preventive behaviors, but less than that needed to accomplish physical activity change in children".[18]

At the mothers' meeting, there was a further attention on making ca-rich girl's diet. To encourage mothers to go along with their daughters to do physical activities, which was recommended at the sessions, to create a background by the basic "equipment" for osteoporosis prevention such as buying calcium-rich foods against harmful substances that excreted calcium and on positive support for the girls. Women are the family health center. They are also responsible for preparing meals and spend more time with their children so they can play an effective role on improving them. On The other hand, mothers are more than concerned children about the future health condition and consequences, so they can play an effective role on improving disease preventive behaviors in their children.

Another component of lifestyle is sun exposure in our study, the mean percentage of desirability of sun exposure quality and quantity improved 13.8% in mother centered group

Table 4: Mean (min/week), SD and *P* value of desirablity of exercise in groups for each time point

Time	Group						*P*
	Mother centered (B)		Daughter centered (A)		Control (C)		
	Mean	SD	Mean	SD	Mean	SD	
Baseline	402.86	259.66	450.08	363.59	426.20	334.70	0.71
4 weeks after the intervention	398.66	238.98	422.46	252.64	416.89	325.72	0.88
2 months	398.34	235.38	418.04	252.13	418.50	328.36	0.79
6 months	401.81	217.27	418.04	245.57	417.57	333.73	0.93
P	0.21		0.63		0.61		

SD = Standard deviation

and 8.34% in daughter centered group after 4 weeks, but this rising was more significant in group B than group A. Both of the intervention groups returned back to the basic score after the 6 months follow-up. In a randomized clinical trial in The Netherlands, subjects were randomly assigned to daily Vitamin D supplementation or advice for sunlight exposure in order to treat Vitamin D deficiency for 3, 6 and 12 months. After 3 months, mean serum 25(OH)D increased in both groups. Though this was more in the supplementation groups than in the advised sunlight group. At 6 months, these measurements were lower than 3 months. At 12 months, the percentage of Vitamin D deficiency (serum 25(OH)D <25 nmol/l) in subjects, was still less than the initial time, except for the sunlight group.[25] Probably the reason for a reduction in the educational impact is "to forget" over the course of the time. Despite knowing the advantages of using sunlight as a strong source of Vitamin D in osteoporosis prevention; few intervention studies have been conducted concerning sun exposure that prevents osteoporosis.

Concerning physical activity, there was no changes in our study at the whole times follow-up. In this field, a high percentage of students did not have satisfactory activities. These findings were supported by the other studies. Kelishadi *et al*., in 2001 in Isfahan, Iran, showed that most of the girls of middle and high schools did not have suitable physical activities.[26] Findings of the other study to promote physical activity in children, revealed that even quite complex and rigorous interventions did not unavoidably increase physical activity.[27] The results of Winzenberg study that examining parental impacts on children's physical activity showed no change on this behavior. Physical activity seems to be a more difficult and complex behavior to change, compared with taking calcium-rich diets. This was shown by the absence of success at improvement physical activity compared to calcium intake in trials specifically trying osteoporosis preventive behavior change.[28] Perhaps education alone, cannot be effective and community-based interventions may be more effective than individual training.

Current policy in Iran's high schools is based on about 2 h of physical activity per week, which cannot meet the needs in the field of osteoporosis prevention. These findings suggest that there is a need for a special attention on a policy level in Education and Training system of Iran to enhance exercise training hours at schools, to create a favorable environment at school, to train educational forces that are able to teach effective exercises related to preventing chronic diseases and to provide sports facilities for girls and also appropriate vehicles for transportation seems essential. Since Iran is a land where there is much sunlight, and Muslim women have limitations, creating specific environments like the parks until they can exercise for a few minutes in the sunlight would be helpful for their health.

CONCLUSION

Although the education about the effectiveness of proper use of nutrition and sun has shown a significant impact on both groups, but this is more effective in mothers group. Hence that such training can be held for mothers at the schools of their daughters. In order to prevent the forgotten and maintaining impact on education, booster sessions with low interval are offered.

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AUTHORS' CONTRIBUTIONS

All authors have contributed in designing and conducting the study. All authors have assisted in preparation of the fi rst draft of the manuscript or revising it critically for important intellectual content. All authors have read and approved the content of the manuscript and confi rmed the accuracy or integrity of any part of the work.

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