Effects of Soy on Body Composition: A 12-Week Randomized Controlled Trial among Iranian Elderly Women with Metabolic Syndrome

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Abstract

Background: To examine the effects of soy [in the form of textured soy protein (TSP) and soy-nut] on body composition in elderly women with metabolic syndrome (MetS).

Methods: A 12-week randomized clinical trial was conducted on 75 women between 60-70 years of age with MetS in rural health clinics around Babol, Iran in 2009. The participants were randomly assigned to one of the three groups of soy-nut (35g/d), TSP (35g/d) and control. Body fat, lean mass and anthropometric indicators were measured before and after intervention, too.

Results: Participants were classified as overweight and showing android fat distribution. After 12 weeks of intervention, both soy-nut and TSP groups showed an increase of non-significant in lean mass (0.9 and 0.7 kg), hip circumference (0.45 and 0.28 cm), triceps skinfold (TSF) thickness (0.87 and 0.67mm) and reduction in BMI (-0.15 and -0.33), waist circumference (-0.83 and -1.2) and body fat (-1.5% and -1.7%). Significant increase in the mean change of TSF and lean mass was observed in the users of soy-nut compared to the control group ($P<0.01$, $P<0.05$).

Conclusion: 12-week intervention of soy had a mild favorable effect on body composition in elderly women with MetS.

Keywords: Soy, Metabolic syndrome, Body composition, Older women

Introduction

Aging is associated with several physiological changes. One of them is a change in body composition, which is characterized by an increase in abdominal obesity and fat mass and a decrease in lean mass (1). These changes in body composition and metabolic effects indicate an increase the risk of serious diseases and subsequent loss of functional capacity and independence (2). On the

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other hand, aging is considered as a major risk factor for metabolic syndrome (MetS) development; a constellation of cardiovascular disease risk factors, which through increased visceral fat as the underlying cause of this syndrome can cause increased mortality and morbidity in the elderly people (3). An increase in visceral fat is also seen specifically in older women due to the lack of estrogen (2). The use of estrogen during the postmenopausal period might have beneficial effects on body fat distribution (4, 5). However, hormone therapy is associated with some serious side effects, therefore its risk to benefit ratio is discussed (6).

Soy products as rich sources of phytoestrogen may be a good substitute for creating beneficial effect on regional body fat and lean tissue distribution. Soy is rich in isoflavone, dietary fiber, leading to increased satiety. Therefore, soy-based foods help reduce fat mass (7). Reports on the effects of soy isoflavone on body composition in elderly women are sparse. Experimental studies on animals showed its beneficial effects (8-10), while clinical studies have shown controversial results (7, 11-13). To the best of our knowledge, no comprehensive reports are available comparing the effects of soy-nut, the natural state of soybean, with textured soy protein (TSP) as a processed soy product on body composition of women above 60 years old with MetS.

This research is aimed to evaluates the effects of two types of soy on weight, BMI (body mass index), circumferences, TSF, fat mass and lean mass among older women with the MetS.

Materials and Methods

In July 2009, a cohort of 240 potential participants was recruited through community advertisement. Posters were distributed in the Rural Health Clinics affiliated with the Babol University of Medical sciences, Iran. After a primary assessment in terms of exclusion criteria, 200 eligible women between 60-70 years old were selected to be screened for MetS. The MetS was determined according to the criteria set by Adult Treatment Panel (ATP) III guidelines which are as follows: 1) waist circumference >80 cm; 2) serum HDL-C <50 mg/dL; 3) triglyceride ≥150 mg/dL; 4) fasting blood glucose ≥100 mg/dL; and 5) systolic blood pressure ≥130 mmHg and diastolic ≥85 mmHg (14). To be qualified for this study, the subjects had to have at least three of the above-mentioned criteria without having to take any medication for the treatment of diabetes, hypertension, or hyperlipidemia. The exclusion criteria were current or previous use of estrogen therapy, the consumption of soy products or supplements, treatment with insulin or oral hypoglycemic, antilipemic, antihypertensive agents, aspirin, history of CVD, hyper and hypothyroidism, kidney, liver, infectious diseases, cancer, vegetarian, smoking or allergic reaction to soy consumption. Finally, 75 women between 60-70 years old who met the inclusion criteria were chosen for this study.

All participants were provided with the informed written consent form to sign. The present study was approved by the Ethical Committee of the University of Putra Malaysia as well as Babol University of Medical Sciences in Iran.

Study procedures

This study was a 12-week parallel-randomized controlled trial. The data were collected between July and December 2009. A questionnaire on demographic characteristics was completed at baseline. The participants were randomized into three groups by the proportional randomization method using a table of random numbers generated by Microsoft Excel. Group A (n=25) received 35 g soy-nut and group B (n=25) 35 g TSP daily for three months. Group C (n=25), the control group, received nothing instead, since the participants in the treatment groups were consuming natural soy products not pills, so it was impossible to apply any placebo for the control group. Soy-nut and TSP were packed and given to the participants in small 490-gram bags for use in 2 weeks and they were provided a soy dose of 35 grams daily. The participants in group B, were trained how to prepare their meal with TSP. First, TSP was soaked in tepid water for about 2-3 minutes and then drained. Then, it was cooked with tur-

meric powder and limejuice for 2 minutes. The participants were strongly advised to take the completely prepared TSP during the intervention. The soy-nut and TSP used in this study were produced and packed by Max Soy Company in Tehran, Iran. The nutrient composition of soy consumed in the study, based on Max Soy Company analysis, is shown in Table 1.

Table 1: Nutrient composition of soy-nut and TSP used in the intervention

Nutrients per 35 g	Soy-nut	TSP
Protein (g)	13.8	18.2
Fat (g)	8.7	0.45
Total carbohydrate (g)	11.5	11.4
Fiber (g)	10.5	11.9
Isoflavones (mg)	117.2	96.2
Diadzein (mg)	47.6	38.5
Genistein (mg)	60.2	48.8
Glycitein (mg)	9.45	8.9

The participants were asked not to change their habitual diet and physical activity levels during the study period. To assure there were no changes in diet and activity, food intake and physical activity levels were measured at the outset as well as during the intervention in a monthly basis. Each participant brought back her 3-d dietary and physical activity records (recorded as MET-minute/week using IPAQ) every month and submitted them to the researcher. These questionnaires were analyzed to determine the participant's compliance and ensure that there were no changes in diet and physical activity levels throughout the treatment period. The researcher also visited the participants every two weeks and called them up weekly in order to monitor their compliance, and see if they had any complaint about soy or they had any changes in their health status. In every two-week meeting, empty packages were taken back and new packages used for the following period.

Measurements
Participants' height was measured using a stadiometer without shoes to the nearest 0.5 cm. Weight, body fat percent, lean body mass and BMI were measured with composition analyzer (Omron HBF-306 body fat analyzer). We determined abdominal fat indirectly by measuring waist circumference (WC) just above the iliac crest. Hip circumference (HC) was also assessed at the level of the greater trochanter. From these the waist-to-hip ratio and waist-to-height was calculated. These ratios give a measure for upper body adiposity. The mid-arm circumference (MAC) was measured, with the right arm held at a vertical angle (90 degrees), between the tip of the shoulder and elbow bone. Then triceps skinfold (TSF) thickness was measured to the nearest millimeter in this area by lifting a fold of skin and the subcutaneous fat away from the underlying muscle and bone with a skin fold calliper (Holtain, Crymych, UK). Measurements were repeated three times and the mean values were taken. Mid-arm muscle circumference (MAMC) was calculated in mm from the following equation: MAMC (mm) = MAC (mm)−[3.14 x triceps skinfold (mm)] (15). The measurements were recorded before and after the 12-week intervention.

Fasting blood samples were collected from each volunteer for diagnosis of MetS. Five ml of venous blood was collected in test tubes. Serum was separated by centrifugation within 15 minutes of collection. The aliquots were frozen and stored at −80°C for subsequent analyses. The triglyceride levels were measured by Elitech kit from France and HDL-C by Pars Azmoon kit from Iran. FBG was measured on the day of blood collection by use of Pars Azmoon kits from Iran. Measurements were assayed on an autoanalyzer (Mindray–BS300, Nanshan, Shenzhen, China).

A One-way ANOVA was run to compare the baseline and final values of the variables in the three groups. At the same time, a one-way ANOVA was run to determine the mean changes among the groups after 12 weeks of intervention. The mean differences were also determined by comparing mean changes of the groups with one another. A paired *t*-test was also applied to assess changes for the 12-week intervention in each group. The Generalized Linear Model (GLM) repeated measures analysis, two factor mixed design was applied to detect the changes in mean of the

physical activity levels and dietary intake of the participants during the 12-week intervention. The two-tailed *P* value of less than 0.05 was considered significant. The statistical analyses were all performed by using SPSS version 17.

Results

All participants completed the entire the study. Both the soy-nut and TSP were well tolerated.

There was no serious complain on the consumption of soy except for cause of flatulence in small number of individuals. Demographic and clinical characteristics of the women at baseline are presented in Table 2 and 3.

There were no significant differences seen among the groups with regard to any baseline variable. Calculated nutrient content of 3-d diet records according to the participants report is shown in Table 4.

Table 2: Demographic characteristics of participants

Variables	Soy-nut (n=25)	TSP (n=25)	Control (n=25)
Age (mean±SD)	63.8±2.8	64.6±2.9	64.1±2.8
Age of menopause (mean±SD)	48.2±3.9	47.7±4.7	48.6±3.6
Years after menopause (mean±SD)	15.5±3.6	16.8±6	15.5±3.7
Economic Status			
Financial aid than relatives	2 (8)	1 (4)	2 (8)
Lack of financial need	23 (92)	24 (96)	23 (92)
Living Arrangement			
Alone	4 (16)	2 (8)	2 (8)
Husband only	19 (76)	19 (76)	20 (80)
Children	2 (8)	4 (16)	3 (12)
Receiving GP visit for health control (at least once a year)			
Yes	22 (88)	22 (88)	19 (76)
No	3 (12)	3 (12)	6 (24)

Table 3: Clinical characteristics of participants according to metabolic syndrome criteria at the baseline

Variables	Soy-nut	TSP	Control	*P* value
WC	93.3±9.69	91.6±10.92	92.4±14.7	0.87
FBG	104.8± 9.85	104.3 ±11.12	102.5 ±11.44	0.75
TG	212.1± 40.31	211.9 ±42.53	212.6± 48.84	0.99
HDL-C	44.2± 6.76	43.1± 4.71	44.2± 7.25	0.78
SBP	127.3±4.41	127.6±4.48	127.4±4.64	0.97
DBP	79.4± 6.47	80.6± 4.34	81.4 ±6.15	0.48

TSP-textured soy protein, WC-waist circumference, FBG-fasting blood glocuse, TG-ttriglyceride, SBP-systolic blood pressure, DBP-diastolic blood pressure

Table 4: Mean ± SE of macronutrient and micronutrient intake the participants in the treatment and the control groups

| Nutrients | Treatment Groups | | | P.value* |
	Soy-nut (n=25)	TSP (n=25)	Control (n=25)	
Total Energy (kcal)	1943.0± 50.45	1939.0±53.39	1959.0±54.65	0.52
CHO (g)	267.2±30.12	275.3±31.14	277.2±30.11	0.35
Percentage	55.0± 3.19	56.8±4.21	56.6±3.18	
Protein (g)	74.9±8.24	81.4±9.24	79.8±8.52	0.24
Percentage	15.4±3.01	16.8±3.34	16.3±3.15	
Total Fat (g)	63. 9±9.11[a]	56.87±8.52	59±9.73	<0.05
Percentage	29.6± 5.65	26.4±5.35	27.1±5.95	
SFA (g)	11.9±3.81[a]	11.6±2.92[a]	16.5±4.73	<0.001
Percentage	5.5 ±1.78	5.4±1.31	7.6±2.21	
MUFA (g)	20.0±5.21	20.5±5.45	19.6±5.18	0.51
Percentage	9.25±1.56	9.5 ±1.68	9.0±1.54	
PUFA (g)	31.9±7.42[ab]	24.8±6.58	22.8±6.19	<0.001
Percentage	14.8±2.86	11.5±2.44	10.5±2.24	
Fiber (g)	39.3±8.24[a]	40.8±9.21[a]	25.3±5.13	<0.001
Phosphorus (mg)	803.0±20.41[ab]	510.0±21.11	400.2±19.04	<0.001
Potassium (mg)	3684.1±176.44[ab]	2420.2±179.56	2297.0±185.32	<0.001
Calcium (mg)	1110.2±92.34[a]	1080.2±88.45[a]	770.1±76.41	<0.001
Folic Acid (mcg)	170.1±30.15	168.8±27.11	170.8±29.14	0.82
Magnesium (mg)	450.3±5.22[ab]	320.1±5.31	300.0±5.06	<0.001
Zinc (mg)	11.8±5.62	10.2±3.91	10.9±4.73	0.14
Iron (mg)	20.7±6.61	19.7±6.91	20.3±7.8	0.27
Vit A(RE)	8282.1±65.12	8380.3±60.21	8250.5±66.35	0.38
Vit E (mg)	8.4±1.51	8.2±1.52	8.6±1.41	0.22
Vit C (mg)	70.9±12.14	69.1±12.15	72.1±12.11	0.87
Vit B1 (mg)	1.1±0.49	1.2±0.67	1.0±0.59	0.52
Vit B2 (mg)	1.7±0.47	1.4±0.51	1.9±0.42	0.29
Vit B6 (mg)	0.76±0.11	0.71±0.09	0.92±0.12	0.27
VitB12 (mcg)	2.1±0.62	1.9±0.71	2.1±0.60	0.26

Note. TSP, textured soy protein; SE, standard Error; CHO, carbohydrate; SFA, saturated fatty acid; MUFA, monounsaturated fatty acid; PUFA, polyunsaturated fatty acid. Food intake was analysed according to the Iranian food composition table. *Significant time x groups interaction effect ($P<0.05$) (GLM Repeated Measures). (a) Significantly different with the control group; (b) Significantly different with the TSP group

No significant groups' interaction effect was found over time in nutrient intake except for fat intake and some of the micronutrients in the treatment groups than the control group. Table 5 shows the mean values of body composition indicators in all groups at baseline and after 12 weeks of intervention with their changes. At baseline, the participants were classified as overweight showing increased percent of body fat with android distribution (WC > 80cm) and also a reduced lean body mass (<64% of body weight); as features associated with aging intensified with the presence of MetS. The mean change of anthropometric indicators and body fat percent showed no significant differences in the groups, though significant increase was observed in lean mass and TSF between the soy-nut and the control groups ($P<0.05$, $P<0.01$). However, in comparison with baseline values, mean WC, BMI and body fat decreased in the soy-nut (-0.83, -0.15, -1.5%) and TSP (-1.2, -0.33, -1.7%) groups after 12 weeks of intervention.

Table 5: Body composition indicators at baseline and after 12 weeks of intervention (mean ± standard error)

Indicator	Soy-nut group	TSP group	Control group	P values
Weight(kg)				
Baseline	72.1±2.30	69.2±1.58	71±3.36	0.68
Week 12	71.8±2.34	68.3±1.62	70.7±3.35	0.60
Mean change	-0.37±0.19	-0.84±0.24	-0.30±0.19	0.16
BMI (kg/m²)				
Baseline	28.8±3.88	27.5±2.59	28.5±1.19	0.53
Week 12	28.6±0.80	27.2±0.55	28.4±1.18	0.44
Mean change	-0.15±0.07	-0.33±0.09	-0.12±0.07	0.16
Hip circumference (cm)				
Baseline	101.2±1.89	99.8±1.77	99±2.91	0.72
Week 12	101.7±1.70	100±1.61	98.8±2.12	0.53
Mean change	0.45±0.39	0.28±0.32	-0.26±0.48	0.43
Waist circumference (cm)				
Baseline	93.3±1.97	91.6±2.27	92.4±3.21	0.87
Week 12	92.5±1.91	90.3±2.25	91.9±3.34	0.81
Mean change	-0.83±0.45	-1.2±0.0.34	- 0.47±0.32	0.40
Waist/Hip ratio(cm)				
Baseline	0.92±0.01	0.92±0.01	0.93±0.01	0.74
Week 12	0.90±0.01	0.90±0.01	0.93±0.02	0.45
Mean change	-0.012±0.005	-0.014±0.004	-0.002±0.005	0.20
Waist/Height ratio(cm)				
Baseline	0.59±0.01	0.57±0.01	0.58±0.01	0.79
Week 12	0.58±0.01	0.56±0.01	0.58±0.01	0.70
Mean change	-0.005±0.002	-.007±0.002	-0.003±0.002	0.41
Fat mass (%)				
Baseline	40.8±0.96	39.4±0.67	40.5±1.40	0.60
Week 12	39.3±0.97	37.7±0.70	40.3±1.40	0.50
Mean change	-1.5±0.09	-1.7±0.11	-0.20±0.09	0.16
Lean mass (kg)				
Baseline	42.7±0.68	41.9±0.50	42.3±0.89	0.69
Week 12	43.6±0.70	42.6±0.52	42.2±0.90	0.71
Mean change	0.90±0.04*	0.70±0.06	0.10±0.03	<0.05
TSF (mm)				
Baseline	14.3±0.97	14.2±0.75	14.7±1.02	0.92
Week 12	15.2±0.87	14.9±0.71	14.8±1.07	0.94
Mean change	0.87±0.20*	0.67±0.13	0.04±0.02	<0.01
MAMC (mm)				
Baseline	282.1±0.62	266.0±0.57	277.8±0.79	0.20
Week 12	280.6±0.56	264.5±0.55	277.2±0.73	0.15
Mean change	- 0.15±0.18	- 0.14±0.17	-0.06±0.22	0.93

*The two tailed $P< 0.05$ were considered significant. Mean change refers to the change from the baseline.

In addition, there was a mean increase of 0.45 cm in HC in the soy-nut and 0.28 cm in TSP groups. Paired *t*-test showed significant intra-individual improvements for waist/hip ratio, lean mass and TSF in the soy-nut ($P<0.05$, $P<0.05$, $P<0.001$) and TSP groups ($P<0.001$).

Discussion

We observed a mild favorable effect but insignificant of soy-nut and TSP consumption on the changes of weight, BMI, and body fat percent after 12-week intervention in the elderly women with MetS.

Soybeans have been investigated, primarily during the past 10 years, because of their potential effects on the health of postmenopausal women (16). However, to the best knowledge of the authors, there is little information on the effects of different soy products on anthropometric indicators or fat distribution and lean mass in elderly women with MetS. The rationale for studying the effect of soy on body fat distribution was that isoflavone may be bound to estrogenic receptors of fat and lean tissues promoting gynecoid fat deposition (17). Whatever the mechanism is, our data showed that both soy products tend to prevent the accumulation of fat in the abdominal depot and increase fat in the extremities; the pattern that is associated with reduced risk of cardiovascular disease. However, the results reported are conflicting about the effects of soy on body composition. Goodman-Gruen and Kritz-Silverstein investigated the relation between dietary isoflavone intake and body composition in 208 participants at the age of 45 to 74 (12). They found a significant inverse relation between soy consumption and BMI, WC and fat mass as well as no correlation with lean mass, suggesting that an isoflavone-rich diet is associated with reduced body fat and may play a role in the prevention of obesity-related chronic diseases. Liao et al and Deibert et al. obtained similar results (7, 18). They determined the effects of a soy-based low-calorie diet on the weight changes in obese adults for 2 and 6 months and found that the diet can improve body composition; causing lose of fat but preserving muscle mass. Moeller et al. assessed body composition in 69 perimenopausal women randomized to 24 weeks of treatment (either 40 or 20 g/day of soy) and control groups and observed that the soy-rich diet contributed to a greater gain in hip lean mass (13). According to their results, soy pro-

tein supplementation did not prevent abdominal fat deposition. Maesta et al. examined the effect of 25 g soy protein and resistance exercise on body composition of 46 postmenopausal women for 16 weeks. BMI, WC, body fat, and muscle mass did not change during intervention, which was contrary to the view that soy protein has favorable effects on body composition (19).

The reasons for these differences could be due to several factors. First, in most effective trials, administration of soy was associated with a reduced calorie diet or lifestyle education (7,18), while in our study, all participants were on a normal diet. However, it can be concluded that improved lifestyle has the synergistic property on soy effects. Second, most of these studies did not include a non-treatment condition as control group and were considered patterns of caloric restriction as a control group instead. Therefore, the effects of treatment occurred in both groups without significant difference (20-21). Third, normally a major problem in weight loss trials is the existence of high attrition rate that can affect the results (13). Fourth, studies related to soy intake and body composition often have been conducted on obese or overweight people and some researches had shown that subjects with higher weight at baseline were more willing to lose weight, since certain hormones have better response of brain for weight loss in these individuals (18). Fifth, designing the study is an important factor to explain this difference. Some studies in the field of nutrition and weight loss carried out as cross- sectional (21-22). Since the researchers did not exclude completely the possibility of residual confounders from the calculation, the results are not reliable due to inaccurately measured or unmeasured covariates. Therefore, the results of these studies should be confirmed by randomized clinical trials. Sixth, participant age is important in the study. Old people may have different response to treatment because of the fact that with normal aging there is a progressive increase in fat and decrease in fat-free mass, mainly due to loss of skeletal muscle. Consequently, in any given weight, older people, on average, have substantially more body fat than young adults do. In addition, a greater

proportion of body fat in older than young people are intrahepatic, intramuscular, and intra-abdominal (versus subcutaneous), which these changes are associated with increased insulin resistance. These changes may lead to inappropriate response to weight reducing diets in the older people (23). In this context, Kok et al showed that the soy consumption containing 99 mg isoflavone at 12 months among 60-75 years old women did not have any effect on the body composition (11). Liu et al found only a mild favorable effect of soy on body composition during six month intervention that is similar to the results of this study (24).

In addition to visceral adipose tissue, the amount of subcutaneous fat tissue is also attributed to obesity-related to insulin resistance and MetS. It has been suggested that low subcutaneous adipose tissue mass in the extremities may increase the risk of diabetes (25). Greater leg fat mass and TSF thickness may have more protective effect against MetS (26). In line with this hypothesis, the findings of this study have shown that the participants in the soy-nut group had higher HC and TSF than the two other groups, though this increase was significant only for TSF measurement. The mechanism of this performance can be attributed to its content of isoflavone. Studies on humans and animals have shown that E2 treatment can have a important role in reducing the total and intra abdominal and increasing the subcutaneous fat depots, because estrogen seems to inhibit lipolysis only in subcutaneous depots and thereby shifts the assimilation of fat from intra abdominal depots to fat depots (27-28). In the present study, the significant increase in TSF in the soy-nut group is promising because it may be associated with lower odds of the MetS. In agreement with the findings above, we have also found a small but significant increase in lean body mass by soy-nut consumption. It is documented that estrogen may have a direct effect on maintaining various tissue components of fat-free mass. Therefore, it may be a way to prevent or reduce the aging sarcopenia (28).

In conclusion, the findings of this study showed that consuming both types of soy products can have positive effects on improving body fat distri-bution, though this effect was little. However, being consistent in reducing total body fat and abdominal fat and in increasing lean body mass and limb fat, the results are all pointing out that there is a potential capacity of soy in these improvements. Therefore, the use of soy in elderly women can lead to improve MetS complications through improving distribution of body fat; since fat tissue increase is a fundamental cause of this syndrome. On the other hand, due to decrease in adipose tissue accompanied by increase in lean body mass, the use of soy can be promising in reducing the sarcopenia associated with aging.

Ethical Considerations

Ethical issues including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc. have been completely observed by the authors.

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