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Therapeutic Effect of Black Soybean Flour Intervention on Menopausal Symptoms of Women

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A B S T R A C T

The present research was undertaken to evaluate the effect of black soybean flour intervention on menopausal symptoms of postmenopausal women. It was an experimental design with pre and post observations including 46 postmenopausal women of 45-55 years. The women were selected as per inclusion criteria and randomly divided into 2 groups. The women in Experimental group A and B received 50 g/day of raw and germinated black soybean flour, respectively, for consecutive 90 days. Information regarding menopause was collected at the beginning of intervention period and 90 days after initiation of intervention using Menopause-Specific-Quality of Life Questionnaire. The dietary intervention significantly improved the symptoms related to vasomotor, psychological and physical domain but didn't have any significant effect on the symptoms related to sexual and vaginal health domains. The study concludes that incorporation of black soybean flour in daily diet can improve complications of postmenopausal symptoms and improve the quality of life of women.

Introduction

Human life encompasses several developmental and growth transitions like adolescence, adulthood and menopause, some of which, especially menopause, are usually not only biological but also involve social and psychological changes. Menopause is a natural transition experienced by every woman characterized by falling levels of estrogen and progesterone hormones, which involves loss of the reproductive function. WHO (1981) has defined menopause as "the permanent cessation of menstruation in a woman due to loss of ovarian follicular activity".

The three phases of menopause i.e. premenopause, perimenopause and postmenopause comprise about 1/2-1/3rd of a woman's life since the life expectancy of women in developed countries is approximately 84.3 years with the average age for menopause as 50-52 years (Abdollahi *et al.,* 2013). As per Indian Menopause Society, the average age of Indian menopausal women is 47.5 years which is lower than the average age of menopause in the western world i.e. 51 years (Pal *et al.,* 2013).

When women reach menopause, hormonal shifts makes them to face difficulties ranging from symptoms to complications. Menopause may be associated with vasomotor symptoms, psychological symptoms, physical symptoms, vaginal health symptoms, sexual symptoms and many more, which can significantly disrupt their daily activities and their sense of well-being (Abedzadeh *et al.,* 2012). The long-term complications of menopause may include osteoporosis (Betts *et al.,* 2017), cancer (Wu *et al.,* 2008), CVDs (Zhoua *et al.,* 2015), urogenital problems (WHO, 1981) and diabetes mellitus (Ko, 2014) etc.

Women adopt a wide range of coping strategies to manage menopausal symptoms which may include Psychological, social, informational, practical and organisational strategies and changing health behaviours (exercise, sleep, diet) (Grifith *et al.,* 2013). Hormone replacement therapy is an effective treatment available for the relief of menopausal symptoms. However, it is reported that women receiving HRT are likely to have several side effects including increased risk for breast cancer and endometrial cancer, osteoporosis, heart disease, stroke and Alzheimer's disease (Darke, 1996). Many women use plant-based alternatives to manage menopausal symptoms including foods or herbal products containing estrogens.

Soybean and its products being rich in isoflavones (phytoestrogen) have the potential to provide an exogenous source of estrogen for women after menopause and thus proposed as an alternative to conventional hormone therapy (Setchell, 2001). Black soybean (*Glycine max* (L.) Merrill), locally known as *Bhatt/Bhatmash*, is grown in 5734 hectare area of Uttarakhand with the yield and productivity of 5636t and 9.82q/ha, respectively (Hipparagi *et al.,* 2017).

Various studies have reported the antioxidant, antitumor, hepatoprotective, hypolipidemic and estrogenic activity of black soybean along with its role in preventing benign prostrate hypertrophy, prostrate cancers and ovarian cancers (Shah, 2006; Ganeshan and Xu, 2017; Chen *et al.,* 2017).

Despite of having numerous health benefits, black soybean is consumed on a very limited scale in India due to lack of its nutritional and therapeutic importance. Therefore, the present study was undertaken to assess the therapeutic role of processed black soybean flour in ameliorating the menopausal symptoms among postmenopausal women.

Materials and Methods

Locale

The intervention study was carried in district Udham Singh Nagar of Uttarakhand in the year 2018.

Material procurement

Black soybean (VL-63 variety) was procured from Tarai Development Corporation (TDC), Haldi, District U.S. Nagar (Uttarakhand). The seeds of black soybean were cleaned manually to remove foreign materials (dust, dirt, grit and

other impurities), broken and immature soybeans.

Flour development

Two types of flour were developed from black soybean i.e. raw and germinated black soybean flour. For preparation of germinated flour, black soybean grains were washed in clean water followed by overnight soaking and draining. Next day, soaked grains were kept for germination for next 72 hours at 32 ± 2^0C in incubator. Germinated grains were oven-dried at 65 ± 2^0C till completely dried, followed by grinding into flour, sieving through 60 mesh sieve and storing the flour in dry and air tight containers for further use.

Subject selection

Inclusion criteria

Women within age group of 45-55 years with absence of menses for at least 12 months but not more than 5 years, complaining of hot flushes and willing to participate in present research were included in the study.

Exclusion criteria

Women receiving any hormone-replacement therapy for treatment of menopausal symptoms and with history of any degenerative diseases such as myocardial infarction, stroke, congestive heart failure, hepatitis, malignant disease of breast or any suspected estrogen-dependent tumours and endometrial carcinoma were excluded.

Women with known allergy or hypersensitivity to soybean and with habit of drinking alcohol and cigarette smoking were also excluded.

Sample size estimation

Sample size for the present study was estimated using the formula given by Dhulkhed *et al.*, 2008.

$$n = \frac{2(SD)^2 (Z_{\alpha/2} + Z_{\beta})^2}{d^2}$$

where $Z_{\alpha/2}$ {Probability of Type I (Alpha) error} = 1.96 (95% power)

Z_{β} {Probability of Type II (Beta) error} = 0.842 (80% precision)

SD = Standard deviation,

d = difference of means

The required sample was found to be 46. For selection of subjects, door to door survey was conducted in the localities of district Udham Singh Nagar, Uttarakhand. A list of total 157 menopausal women was prepared and they were assessed for their eligibility in the study. Out of 157, 27 women were excluded as they didn't meet the inclusion criteria. Among remaining 130 menopausal women, 50 women were randomly selected using random number tables.

Ethical considerations

Subjects were explained about the nature and purpose of study and a fully informed written consent was taken from each subject. A formal approval was taken from the University Ethics Committee for Human Research (UECHR) G.B. Pant University of Agriculture and Technology, Pantnagar, Uttarakhand.

Study tool

The subjects were interviewed for the socio-demographic information such as name, age, religion, social category, marital status, education, occupation, family type and family size etc using a structured interview schedule. Anthropometric measurements of the subjects (height, weight, mid-upper-arm-circumference, waist and hip circumference)

were taken as per methods described by Jelliffe (1966) using standard equipments. BMI was calculated and subjects were categorized into different categories of nutritional status as per the classification given by WHO (2004).Value of 18.5 was taken as cut-off point of undernourishment for the subjects, while more than equal to 23.0 was considered as an indicator of overweight. Waist-to-hip ratio was calculated from waist and hip circumference measurements. A waist to hip circumference greater than 0.85 in women indicated abdominal adiposity (WHO, 2002).

Information on menopausal symptoms was collected using "Menopause-Specific Quality of Life Questionnaire" developed by Primary Care Research Unit, University of Toronto (Hilditch and Lewis, 1996). The entire questionnaire was divided into five domains i.e. vasomotor, psychosocial, physical, vaginal health and sexual domain. Under each domain, questions related to presence and severity of menopausal symptoms was asked. For each question, subjects had to answer on the basis of problem experienced by them in the last one month.

To ensure the validity of the interview schedule, the preliminary schedule was pilot-tested on 10 menopausal women in the age group of 45-55 years. Thereafter necessary modifications were incorporated and modified interview schedule was used in the present study. The subjects included in the pilot study were not included in the final study. The scoring of each symptom was done using "Likert scoring method" (Kumar *et al.,* 2016) in which score increased point by point with increasing severity of perceived symptoms from 0 (No symptom) to 4 (1–mild, 2–moderate, 3–severe, 4–very severe) in each of the 30 symptom. Mean scores for each symptom in a group and mean score for specific domains were calculated.

Black soybean flour was taken as a product for supplementation in the present study and subjects were instructed to consume 50g black soybean flour per day in the form of chapatti in any of their meals i.e. breakfast, lunch or dinner.

Study design

Subjects were randomly allocated into two groups – Experimental group A and B. Each group consisted of 25 subjects, for whom, the intervention programme was conducted for a period of 90 days. Experimental group A received raw black soybean flour whereas group B received germinated black soybean flour (50g in well sealed zip-lock pouch/day) for 90 days. Regular monitoring of dietary intervention was done either through home visit or telephone call.

All the 50 subjects were examined for menopausal symptoms on zero day i.e. before the initiation of the study. This baseline data served as control for the subjects in the study. It was followed by supplementation period of ninety days.

Four subjects quit in-between the study, due to personal reasons and finally the dietary intervention was completed by only 46 subjects. On completion of ninetieth day, all the 46 subjects were again examined for menopausal symptoms after intervention (Figure 1).

Statistical analysis

The data on all the menopausal symptoms was analyzed statistically (Snedecor and Cochran, 1967). Paired t-test was applied between the 'baseline' and 'after intervention' values of a parameter of individual subjects. Two-sample t-test was used to find out the significance of difference between the two experimental groups for various parameters.

Results and Discussion

Characteristics of the study population

The study included 46 postmenopausal women aged 45-55 years. Majority of the subjects belonged to the Hindu religion (93.48%) and were married (80.43%). The data on education of subjects (Table 1) revealed that majority i.e. 43.48% subjects were educated up to post graduation and above, followed by 15.21 and 10.87% subjects who were educated up to primary and graduation levels, respectively. More than half i.e. 56.52% subjects were housewives who were not involved in income generation outside. Rest about 43.48% subjects was employed.

Majority i.e. 65.22% subjects belonged to nuclear families. More than 72% subjects had small family size having 1-4 members, followed by 21.74% of families having 5-8 members. Per capita income of the study population ranged from Rs. 2500-81250 per month. The factors responsible for higher per capita income in the present study might be the more number of nuclear families with majority of subjects having small family size.

Anthropometric measurements of study population

Anthropometric details of study population are presented in table 2. The data showed that height and weight of subjects varied from 137.80-161.30cm and 43.60-104.40kg with the mean height of 151.80±5.64cm and mean weight of 63.81±9.80kg, respectively. The mean BMI of subjects was 27.70±4.08kg/m^2. Distribution of subjects on the basis of BMI data showed that majority of the subjects were pre-obese (58.7%), followed by 17.39% women categorized as obese grade I (Figure 3). The mean MUAC, waist circumference and hip circumference of the subjects in the present study was 30.13±3.21cm, 98.45±10.13cm 103.64±8.38cm, respectively. In the present study, WHR of subjects varied from 0.83-1.24 with 86.96% subjects having abdominal obesity.

Mean age at menopause

The findings of the present study revealed that mean age of menopause was 48.42±2.77 and 49.13±2.85years for subjects of groups A and B, respectively.

Impact of dietary intervention of black soybean flour on menopausal symptoms

Vasomotor domain

Figure 2 represents severity of vasomotor domain symptoms of the subjects which included hot flushes and nocturnal sweating. Data on intensity of hot flushes showed that before dietary intervention 27.3 and 29.2% subjects of groups A and B experienced ‘very severe’ hot flushes which reduced to 4.6 and 12.5%, respectively, after intervention. Nocturnal sweating was reported only by 36.96% subjects of the study.

Severe intensity of nocturnal sweating was reported by 40.9 and 25% subjects before intervention which reduced to 27.3 and 16.67%, respectively. On comparison of mean scores (Table 3) at baseline and after intervention, significant ($p \leq 0.05$) decreases of 26.95 and 34.61% were observed in groups A and B, respectively. The mean scores of vasomotor symptoms reported by subjects of both the groups were found non-significantly ($p \leq 0.05$) different from each other.

Psychological domain

The findings of the study (Table 4) showed that decrease in work performance, poor memory, lack of drive for work and

anxiousness were the most common problems reported by subjects under psychological domain. The overall mean score of psychological domain at baseline showed significant ($p \leq 0.05$) reductions of 23.65 and 26.63% in group A and B, respectively after intervention. A non-significant ($p \leq 0.05$) difference was observed in the overall mean score of psychological domain in both groups. None of the subjects reported "very severe" intensity of symptom under psychological domain.

Physical domain

In the present study, the most commonly observed physical domain symptoms were feeling of tiredness (82.6% subjects), decrease in physical strength (89.1%), muscles/joints ache (80.4%), dry skin (82.6%) and bladder inconsistence (67.4%) (Table 5). The overall mean score of physical domain in group A and group B at baseline showed significant ($p \leq 0.05$) reductions of 43.62 and 42.85% after the dietary interventions of raw and germinated black soybean flours, respectively. A non-significant ($p \leq 0.05$) difference was observed in the mean scores of physical domain of groups A and B. None of the subjects reported "very severe" intensity of symptom under physical domain.

Postmenopausal women have an increased tendency for gaining weight. In the present study, data on the weight gain after menopause showed a wide range of 0 to 15kg. About 46 and 26% subjects reported mild (1-5kg) and moderate (5-10kg) weight gain after menopause while 26% subjects didn't report any weight gain after menopause.

Vaginal health domain and sexual domain

The vaginal health domain included symptoms like vaginal itching, vaginal discharge, vaginal pain or bleeding during sex. The overall mean scores of vaginal health symptoms viz vaginal itching and vaginal discharge decreased non-significantly ($p \leq 0.05$) from 0.36 to 0.32 in group A and from 0.29 to 0.25 in group B, respectively, after intervention (Table 6). None of the subjects complained about the vaginal bleeding in the present study. Also, the mean scores of vaginal health symptoms reported by subjects of two groups were found to be non-significantly ($p \leq 0.05$) different from each other.

The sexual domain symptoms included decreased sexual desire, avoiding intimacy with husband and satisfaction after sex. The findings of the present study showed no significant ($p \leq 0.05$) improvement in sexual problems. An increase of 23.91% in percentage of subjects with loss of libido (decrease in sexual desire) was observed after the dietary intervention (Table 7). The findings concluded that the dietary intervention of raw and germinated black soybean flour didn't have any positive role in improving sexual problems related with postmenopausal stage.

The data on overall changes in the severity of menopausal symptoms perceived by the subjects showed maximum improvement in symptoms of physical domain, followed by the psychological domain, vaginal health and vasomotor domain as 95.65, 80.43, 76.09 and 71.74% subjects, respectively, reported positive change in menopausal symptoms. Negative change was not at all reported by the subjects.

The present study investigated the prevalence of menopausal symptoms in postmenopausal women aged 45–55years of Uttarakhand state. Under anthropometric measurements, mean height of subjects in the present study was found lower than the reference height of 161cm (ICMR, 2010) for Indian women. Dobhal and Raghuvanshi (2008) reported the

mean height and weight of adult women of Uttarakhand as 154cm and 50.76kg. Based on BMI classification, Patel *et al.,* (2016) and Sen and Verma (2016) reported the prevalence of overweight/obesity in 61 and 44% women, respectively. WHR indicates the prevalence of visceral fat i.e. the dangerous internal fat coating the organs. Patricia *et al.,* (2011) and Sen and Verma (2016) reported the mean WHR of menopausal women as 0.81±0.08 and 0.90±0.1.

The mean age at menopause in the present study was found to be 48.79±2.80years. This is consistent with the study results of Randhawa and Sindhu (2014) and Madhukumar *et al.,* (2012) in different parts of India as 48.86±2.12 and 49.33years, respectively. Various studies have reported the age of menopause in women of different countries varying from 44.7 years (Mansour *et al.,* 2014) to 50.9years (Meschia *et al.,* 2000). The wide variation in the age of menopause in women may probably be because of regional, community and ethnic variations, genetic and environment factors.

Hot flushes and nocturnal sweating are the classical symptoms of menopause. In the present study, all the subjects were experiencing hot flushes and 63.04% reported nocturnal sweating. Hot flush is described as a sensation of heat in the upper body (face, neck, chest and arms) often followed by sweating and chills, and may be accompanied by palpitation, fatigue, irritability, anxiety, and panic (Zhang *et al.,* 2009). Hot flushes occurrence might be due to the narrowing of the inter threshold zone (within the hypothalamic thermoregulatory zone) during menopause, which is defined as the threshold between sweating and shivering (Stearns *et al.,* 2002). Another mechanism for the hot flush might be the result of elevated body temperature leading to cutaneous vasodilatation, leading to flushing or sweating in association with a decrease in temperature and chills (Goodman *et al.,* 2011).

Various studies have reported the percentage of postmenopausal women experiencing hot flushes as 44.3 (Gyawali *et al.,* 2016), 60 (Karmarkar *et al.,* 2018) and 70.6% (Masjoudi *et al.,* 2017). The beneficial effect of dietary soybean products in reducing hot flushes in menopausal women has been reported by Salvador *et al.,* (2016). A longitudinal, multicentric, multiethnic, community study conducted by Green *et al.,* (2009) included menopausal women from different countries. The results showed that the prevalence of combined hot flushes and night sweating was lowest among women of Japanese (18%) origin, while increasing among Chinese (21%), Caucasian (31%), Hispanic (35%), and African Americans (46%). It was hypothesized that diet plays a role in the type and severity of menopausal symptoms. It was found that a diet high in phytoestrogens protects against vasomotor symptoms. Soybean is a rich source of phytoestrogens. A typical Japanese diet contains high amounts of soybean, and this might be associated with a decrease in vasomotor symptoms.

In the current study, the most common psychological symptoms found were lack of drive to do work (80.4%), decrease in wok performance (78.3%), anxiousness (73.9%) and poor memory (73.9%). A study done by Bairy *et al.,* (2009) showed high prevalence of aching in muscles and joints (67.7%), feeling tired (64.8%), poor memory (60.5%), lower backache (58.8%), feeling bloated (55.1%), and difficulty in sleeping (51.7%) among the postmenopausal respondents. Lu *et al.,* (2007) conducted a cross-sectional survey in Australia among women aged 45-65 years and reported “feeling of tiredness” (86%) and “aching in muscles and joints” (85%) as most frequent symptoms.

Table.1 General profile of the subjects

(N=46)

Characteristic	per cent	Characteristic	per cent
Age (Years)		**Religion**	
45-50	36.96	Hindu	93.48
50-55	63.04	Muslim	6.52
Occupation of the subject		**Marital status**	
Employed	43.48	Married	80.43
Unemployed	56.52	Widow	19.57
Family type		**Family size**	
Nuclear	65.22	Small (1-4 members)	73.91
Joint	2.17	Medium (5-8 members)	21.74
Extended	32.61	Large (>8 members)	4.35
Education		**Per capita monthly income (Rs.)**	
Illiterate	8.70	1000-10000	34.78
Primary	15.21	10000-20000	30.43
Junior High School	4.34	20000-30000	15.22
High School	8.70	30000-40000	10.87
Intermediate	8.70	40000-50000	4.35
Graduation	10.87	50000-60000	2.17
Post graduation and above	43.48	>80000	2.17

Table.2 Anthropometric parameters of subjects

Parameters	Mean value	Range
Height (cm)	151.80±5.64	137.80-161.30
Weight (kg)	63.81±9.80	43.60-104.40
BMI (kg/m^2)	27.70±4.08	20.04-44.60
Waist circumference (cm)	98.45±10.13	73.70-122.50
Hip circumference (cm)	103.64±8.38	77.20-131.30
WHR	0.95±0.07	0.83-1.24
MUAC (cm)	30.13±3.21	22.40-41.30

Values represent mean ± SE

Table.3 Mean scores of menopausal symptoms of the subjects before and after the dietary intervention

Symptoms	Groups	Baseline	Final	% Change	Paired *t*-value
Vasomotor domain	A	4.86±2.27	3.55±1.95	26.95	6.22*
	B	4.71±2.33	3.08±1.74	34.61	5.42*
	t_{AB}-value	0.23 NS	0.85 NS		
Psychological domain	A	9.64±3.82	7.36±2.48	23.65	5.59*
	B	8.75±4.94	6.42±3.59	26.63	5.93*
	t_{AB}-value	0.68 NS	1.05 NS		
Physical domain	A	11.05±5.67	6.23±3.41	43.62	7.87*
	B	11.88±5.33	6.79±3.67	42.85	9.11*
	t_{AB}-value	0.51 NS	0.54 NS		
Vaginal domain	A	0.41±0.16	0.37±0.12	31.71	1.37NS
	B	0.54±0.20	0.49±0.13	27.78	1.36NS
	t_{AB}-value	0.49 NS	0.80 NS		

Group A= Intervened with raw black soybean flour (22 subjects), Group B= Intervened with germinated black soybean flour (24 subjects), - Values not reported, t_{AB}-value shows the comparison between group A and group B, * shows significant difference between values at 5% level of significance, NS: non-significant

Table.4 Effect of dietary intervention on menopausal symptoms of psychological domain

Symptoms	Groups	Before intervention (%)					After intervention (%)				
		3	2	1	0	Mean	3	2	1	0	Mean
Depression	**A**	4.6	9.1	45.5	40.9	**0.77**	4.6	0	54.5	40.9	**0.68**
	B	-	25	29.2	45.8	**0.79**	-	16.7	37.5	45.8	**0.71**
Lack of drive for work	**A**	13.6	45.5	22.7	18.2	**1.18**	-	31.8	50	18.2	**1.14**
	B	8.3	45.8	25	20.8	**1.42**	-	20.8	58.3	20.8	**1.00**
Feeling of wanting to be alone	**A**	-	4.55	27.3	68.2	**0.36**	-	0	31.8	68.2	**0.32**
	B	-	4.2	25	70.8	**0.33**	-	0	29.2	70.8	**0.29**
Dissatisfaction with personal life	**A**	4.6	4.6	13.6	77.3	**0.36**	-	4.6	13.6	81.8	**0.23**
	B	-	16.7	4.2	79.2	**0.38**	-	8.3	12.5	79.2	**0.29**
Anxiousness	**A**	-	31.8	50	18.2	**1.14**	-	13.6	59.1	27.3	**0.86**
	B	4.2	25	37.5	33.3	**1.00**	-	12.5	58.3	29.2	**0.83**
Impatience	**A**	-	31.8	22.7	45.5	**0.86**	-	13.6	40.9	45.5	**0.68**
	B	-	16.7	12.5	70.8	**0.46**	-	4.2	25	70.8	**0.33**
Decrease in work performance	**A**	18.2	50	9.1	22.7	**1.64**	-	36.4	40.9	22.7	**1.14**
	B	4.2	50	25	20.8	**1.38**	-	20.8	58.3	20.8	**1.00**
Experiencing poor memory	**A**	4.6	45.5	27.3	22.7	**1.32**	-	31.8	50	18.2	**1.14**
	B	4.2	33.3	33.3	29.2	**1.13**	-	29.2	50	20.8	**1.08**
Difficulty in falling asleep	**A**	13.6	31.8	9.1	45.5	**1.14**	-	13.6	36.4	50	**0.64**
	B	12.5	25	4.2	58.3	**0.92**	-	16.7	25	58.3	**0.58**
Difficulty in sleeping through	**A**	22.7	22.7	9.1	45.5	**1.23**	-	-	31.8	68.2	**0.32**
	B	16.7	20.8	4.2	58.3	**0.96**	-	-	33.3	66.7	**0.33**

3=Severe, 2=Moderate, 1= Mild, 0=None, Group A= Intervened with raw black soybean flour (22 subjects), Group B= Intervened with germinated black soybean flour (24 subjects), - Values not reported

Table.5 Effect of dietary intervention on menopausal symptoms of physical domain

Symptoms	Groups	Before intervention (%)					After intervention (%)				
		3	2	1	0	Mean	3	2	1	0	Mean
Muscles/joints ache	**A**	36.4	22.7	13.6	27.3	**1.68**	9.1	45.5	18.2	27.3	**1.36**
	B	45.8	29.2	12.5	12.5	**2.08**	25	37.5	25	12.5	**1.75**
Tiredness	**A**	40.9	31.8	4.5	22.7	**1.91**	-	4.6	45.5	50	**0.55**
	B	41.7	33.3	12.5	12.5	**2.04**	-	4.2	58.3	37.5	**0.67**
Head/ neck ache	**A**	31.8	18.2	18.2	31.8	**1.50**	9.1	31.8	27.3	31.8	**1.18**
	B	16.7	33.3	16.7	33.3	**1.33**	8.3	29.2	25	37.5	**1.08**
Flatulence	**A**	4.5	13.6	59.1	22.7	**1.00**	-	9.1	72.7	18.2	**0.91**
	B	-	25	41.7	33.3	**0.75**	-	12.5	50	37.5	**0.75**
Decrease in physical stamina	**A**	22.7	45.5	22.7	9.1	**1.82**	-	4.6	31.8	63.7	**0.41**
	B	12.5	58.3	16.7	12.5	**1.71**	-	-	50	50	**0.5**
Dry skin	**A**	13.6	50	13.6	22.7	**1.55**	-	9.1	50	40.9	**0.68**
	B	8.3	37.5	41.7	12.5	**1.42**	-	8.33	50	41.7	**0.67**
Increased facial hair	**A**	-	13.6	-	86.4	**0.27**	-	13.6	-	86.4	**0.27**
	B	-	12.5	-	87.5	**0.25**	-	12.5	-	87.5	**0.25**
Pain during urination	**A**	-	13.6	4.5	81.8	**0.32**	-	-	13.6	86.4	**0.14**
	B	-	8.3	12.5	79.2	**0.29**	-	-	20.8	79.2	**0.21**
Increased need to urinate	**A**	-	9.1	27.3	63.6	**0.45**	-	9.1	18.2	72.7	**0.36**
	B	-	12.5	16.7	70.8	**0.42**	-	12.5	-	87.5	**0.25**
Bladder inconsistence	**A**	18.2	18.2	13.6	50	**1.05**	-	4.6	40.9	54.6	**0.50**
	B	8.3	20.8	4.2	66.7	**0.71**	-	8.3	25	66.7	**0.42**

3=Severe, 2=Moderate, 1= Mild, 0=None, Group A= Intervened with raw black soybean flour (22 subjects), Group B= Intervened with germinated black soybean flour (24 subjects), - Values not reported

Table.6 Effect of dietary intervention on menopausal symptoms of vaginal health domain

Symptoms	Severity	Group A		Group B	
		Before int.	After int.	Before int.	After int.
Vaginal itching	Severe (3)	-	-	-	-
	Moderate (2)	13.6	9.1	8.3	4.2
	Mild (1)	9.1	13.5	12.5	16.7
	Nil (0)	77.3	77.3	79.2	79.2
	Mean	**0.36**	**0.32**	**0.29**	**0.25**
Vaginal discharge	Severe (3)	-	-	4.2	-
	Moderate (2)	9.1	4.5	4.2	8.3
	Mild (1)	-	4.5	12.5	12.5
	Nil (0)	90.9	90.9	79.2	79.2
	Mean	**0.18**	**0.14**	**0.33**	**0.29**
Vaginal pain during intercourse	Yes	9.1	9.1	16.7	16.7
	No	63.6	68.2	54.2	54.2
	No comment	9.1	4.6	8.3	8.3
	Not applicable	18.2	18.2	20.8	20.8
Vaginal bleeding during intercourse	Yes	-	-	-	-
	No	72.7	72.7	70.8	70.8
	No comment	9.1	9.1	8.3	8.3
	Not applicable	18.2	18.2	20.8	20.8

Group A= Intervened with raw black soybean flour (22 subjects), Group B= Intervened with germinated black soybean flour (24 subjects), - Values not reported

Table.7 Effect of dietary intervention on menopausal symptoms of sexual domain

Symptoms	Group A		Group B	
	Before int.	After int.	Before int.	After int.
Decreased sexual desire (Loss of libido)				
Yes	13.6	63.6	50	50
No	13.6	13.6	20.8	16.7
No comment	9.1	4.6	8.3	12.5
Not applicable	18.2	18.2	20.8	20.8
Avoiding intimacy with husband				
Yes	40.9	31.8	29.2	37.5
No	31.8	36.4	41.7	33.3
No comment	9.1	13.6	8.3	8.3
Not applicable	18.2	18.2	20.8	20.8
Satisfaction after sex				
Yes	27.3	22.7	29.2	33.3
No	45.5	31.8	41.7	29.2
No comment	9.1	27.3	8.3	16.7
Not applicable	18.2	18.2	20.8	20.8

Group A= Intervened with raw black soybean flour (22 subjects), Group B= Intervened with germinated black soybean flour (24 subjects), - Values not reported

Fig.1 Study design

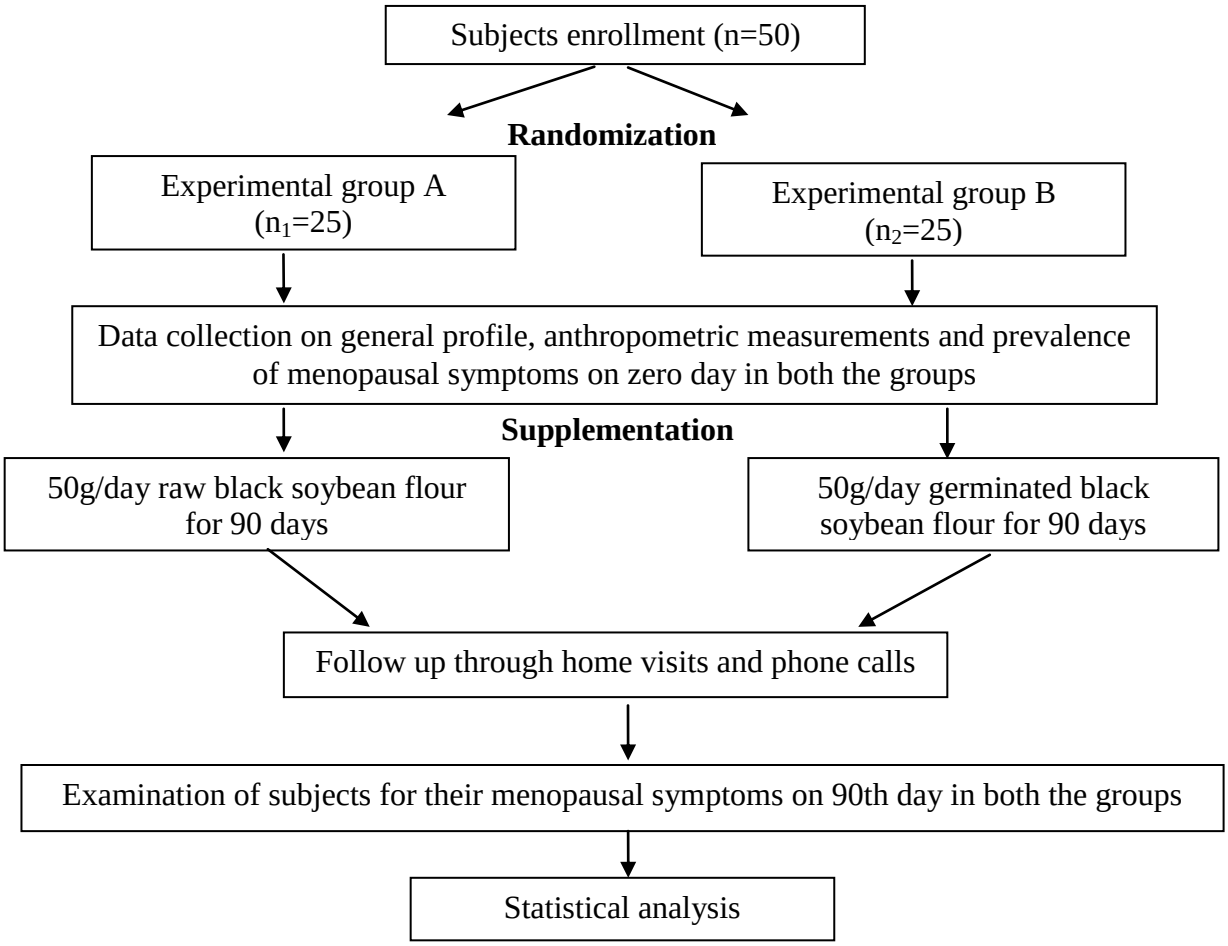


Fig.2 Effect of dietary intervention on vasomotor symptoms of subjects

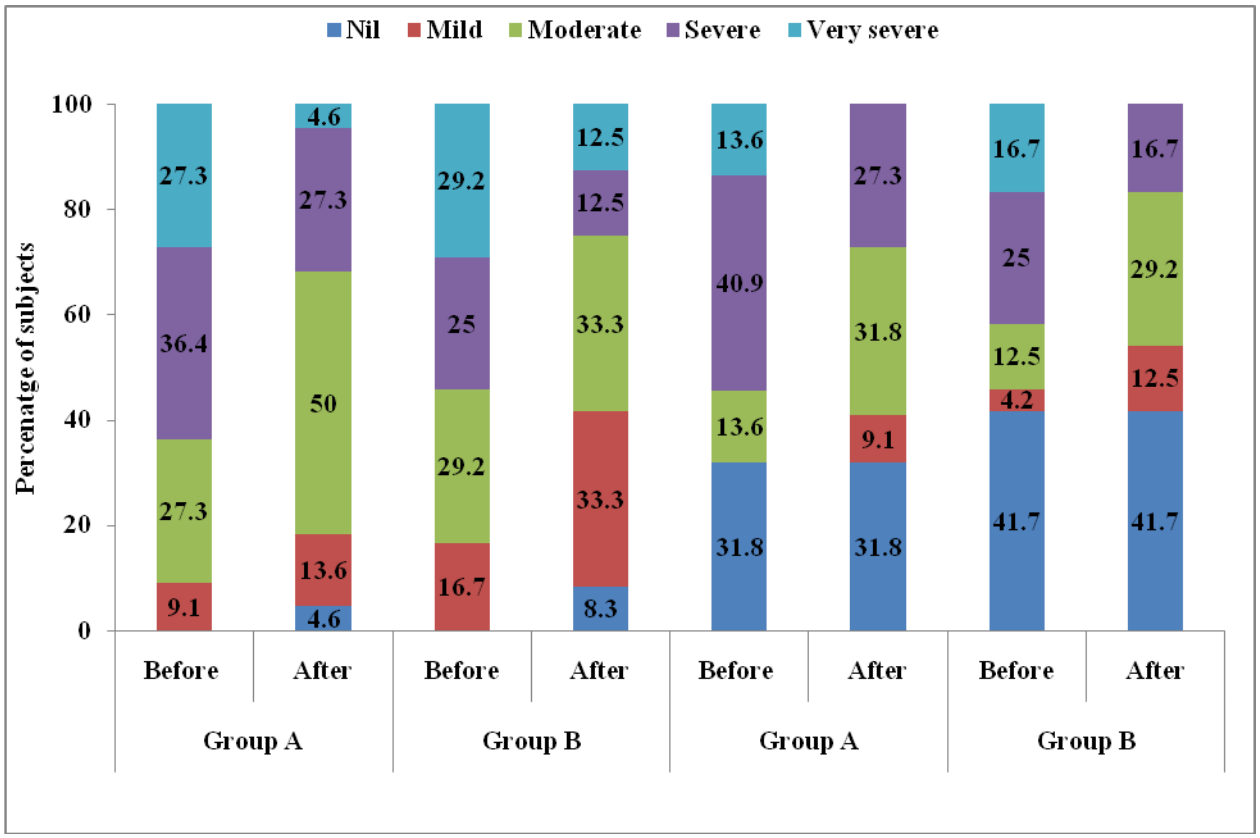
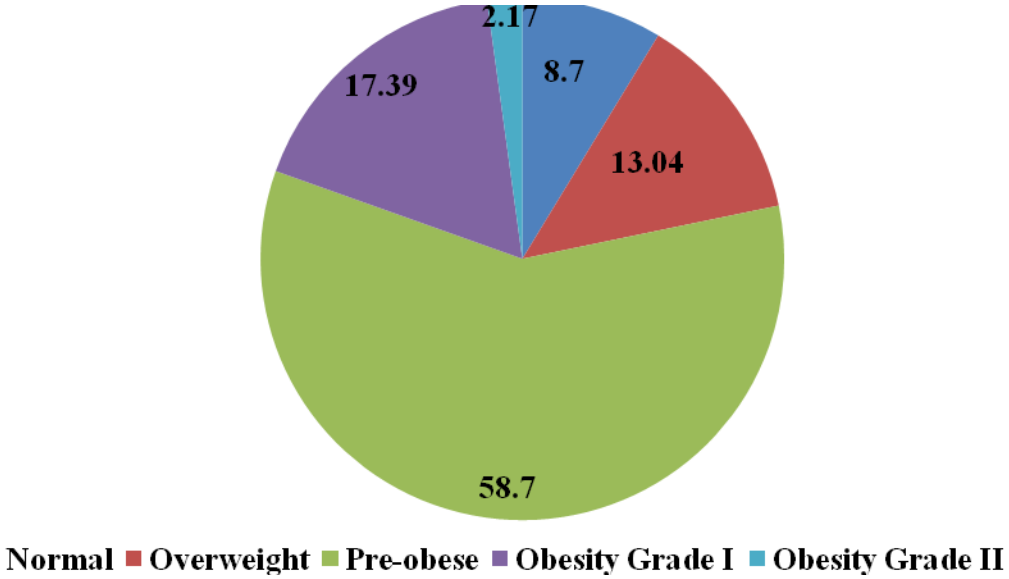


Fig.3 Classification of subjects on the basis of Body Mass Index (BMI)



Postmenopausal women have an increased tendency for gaining weight. The reason might be attributed the declining levels of estrogen which leads to change in fat distribution (Rosano *et al.,* 2007) from gynoid to android as well the physical inactivity. Mandal and Chaudhuri (2010) reported significant positive correlation of estrogen levels with breadth and circumference measures of trunk, thigh circumference and with body weight.

A descriptive cross-sectional study conducted by Karmakar *et al.,* (2018) reported lack of energy (93%), decrease in stamina (88%), aches in neck or head (76%), low backache (69%), frequent urination (63%), drying skin and changes in appearance, texture, tone of skin (40%) being the most commonly reported physical symptoms. Masjoudi *et al.,* (2017) reported the muscle/joint problem (82.7%) being the major problem related to physical domain.

Various studies have reported symptoms under physical domain including joint and muscular pain in the range of 15.90 (Asadi *et al.,* 2012) to 89.50% (Ahlawat *et al.,* 2016) and physical exhaustion in the range of 29.30 (Gyawali *et al.,* 2016) to 93% (Goyal *et al.,* 2012). Bladder problems varies from 8.1(Ahlawat *et al.,* 2016) to 63% (Karmakar *et al.,* 2017) with the common symptoms of frequent urination and bladder inconsistence. The common urogenital symptoms i.e. vaginal dryness/itching and change in sexual desire has been reported in the range of 6.70-41.10% (Ahlawat *et al.,* 2016; Asadi *et al.,* 2012) and 11.40-49% (Gyawali *et al.,* 2010; Karmakar *et al.,* 2017), respectively. During premenopausal period, estrogen promotes vaginal colonization by lactobacilli that metabolizing glycogen and producing lactic acid, and maintains intravaginal health by lowering the intravaginal pH level. A lower vaginal pH inhibits uropathogen growth, preventing vaginal infections. Decreased estrogen secretion in postmenopausal women depletes lactobacilli and increases intravaginal pH, resulting in increased vaginal colonization by harmful microorganisms (Larsen and Monif, 2001). Lower prevalence of vaginal symptoms in the subjects of present study might also be attributed to their higher consumption of curd and its products like *raita, kadhi* etc. with a frequency of more than thrice in a week in about 62% subjects.

Curd is a rich source of *lactobacillus* and *streptococcu*s bacteria which have been proven to positively affect the vaginal microflora composition by promoting the proliferation of beneficial microorganisms, altering the intravaginal microbiota composition, preventing vaginal infections and its symptoms in postmenopausal women (Kim and Prak, 2017). The findings of the present study are similar to study by Petricevic *et al.,* (2008) who showed the beneficial role of probiotics (*lactobacilli*, once daily for 2 weeks) in improving the vaginal flora of postmenopausal women.

None of the subjects reported negative change (increase in severity) in any of the symptoms of five domains with the dietary intervention of black soybean flour. The overall improvement in menopausal symptoms of subjects might be attributed to the antioxidant property of the black soybean flour which contains high contents of α-tocopherol, isoflavones, flavonoids and anthocyanins, possessing high biological activity (Kumar *et al.,* 2010). Dobhal (2018) reported the antioxidant activity of raw and germinated black soybean flour as 65.52 and 52.77%, respectively, which is higher than the values reported by Malencic *et al.,* (2007) in yellow soybean. This result implies that black soybean intake on regular basis is beneficial in ameliorating the menopausal symptoms with no adverse effects on severity of menopausal symptoms in postmenopausal women.

The present study investigated the palliative effect of black soybean flour on menopausal symptoms of postmenopausal women. The results indicated that menopausal symptoms under physical, psychological and vasomotor domain showed significant improvement with dietary intervention while symptoms of vaginal health and sexual domains didn't show any significant improvement. None of the subjects reported negative effect of the dietary intervention which implies that black soybean intake on regular basis is beneficial in ameliorating the menopausal symptoms with no adverse effects. Hence, it is recommended to encourage incorporation of black soybean flour in daily diet as it can as improve complications among postmenopausal women and improve their quality of life.

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