



**EFFECT OF PHYTOESTROGEN (FLAX SEEDS) ON
PERIMENOPAUSAL & MENOPAUSAL SYMPTOMS IN FEMALES
RESIDING IN FARIDABAD**

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ABSTRACT

The term “Menopause symptoms” can describe any of the changes a woman goes through either just before or after menstruation cessation due to the lack of estrogen hormone. Phytoestrogens are plant-derived compounds that structurally or functionally mimic mammalian estrogen and available in flax seeds in good amount. Present study was conducted to assess the effect of phytoestrogen (Flax seeds) on menopausal symptoms. Total 40 subjects were recruited and were equally divided in to two group- Group 1(flax seeds-20 gms) and Group 2(placebo). Baseline data was collected using pretested questionnaire, which comprised demographic, anthropometric, medical and dietary profile. Menopausal symptoms severity was recorded using Heinmann’s menopausal rating scale (MRS) at baseline and at last follow-up (30-days). At base line, both the groups were comparable. Hot flushes, heart discomfort, sleeping disorder, urinary complaints, depression and physical-mental exhaustion symptoms severity get reduced after intervention of flax seeds. So the present study concluded that flax seeds might be beneficial for some menopausal symptoms. But the present findings warrant confirmation by doing longitudinal studies on larger number of samples.

KEYWORDS: menopause, flax seeds, phytoestrogen.

INTRODUCTION

Menopause is a natural biological process that occurs in every woman’s life. It marks the permanent end of monthly periods (menstruation) and fertility. This means she is no longer

able to have children. During this transition period, a woman's ovaries stop making eggs and her body produces less estrogen and progesterone. Menopause is confirmed when a woman has no period for 12 months in a row.^[1]

The symptoms and signs of menopause generally appear well before that one-year period is over. They may include: Irregular Periods, Lower fertility, Vaginal dryness, Hot flashes (UK term: hot flushes), Night sweats, Disturbed sleep, Urinary problems, Moodiness, Problems focusing and learning, More fat building up in the abdomen, Hair loss (thinning hair), Loss of breast size.^[2] The conventional treatment for menopausal symptoms is hormone replacement therapy. Hormone replacement therapy may be good in relieving some of those torturous menopausal symptoms by replacing the lost hormone in the female body, but analysis from the women's health initiatives indicates that combination hormone therapy increases cancer and heart diseases risk. Phytoestrogens are natural plant substances with a structural and functional similarity to genuine 17 β -estradiol. They are mainly absorbed by daily nutrition and are principally categorized in two biochemical classes Lignans: Enterolacton and Enterodiol. Flaxseed, or Linseed (*Linum Usitatissimum*), popularly known as Alsi, Jawas, Aksebija in Indian languages, is a blue flowering rabi crop and a member of family Linaceae^[3] are rich source of phytoestrogens and have similar action as of estrogen in human body.

With the above background, present study was conducted with the aim to assess the effect of phytoestrogens intake in the form of Flax seeds instead of hormone replacement therapy on menopausal symptoms of women.

METHOD AND MATERIAL

The methodology of present study was divided in to 3 phases. Phase I (Subject selection), 40 women of age 45-60 yrs who had menopausal complaints or irregular menstrual cycle were recruited from Gynecology clinic after assessing an inclusion and exclusion criteria. Inclusion criteria were 1) women should have irregular menstrual cycle (Perimenopausal stage), menstrual cycles stopped in last 5 year, 2) who were ready for the intervention of flax seeds. Exclusion criteria were 1) women who had surgical hysterectomy, 2) menstrual cycle was stop from more than five year, 3) women who are not willing to take intervention 4) women had any other complications like Hypothyroidism, Hyperthyroidism and 5) women were on hormonal treatment. All the recruited subjects (n=40) were randomized in to two groups of 20 subjects- Group 1 (Flax seeds) and Group 2 (placebo).

Phase II (intervention), group 1 were intervened by 10 gm of flax seed two times/day and group 2 were with placebo for 30 days. A pretested questionnaire was used for collecting the general information (age, sex, family income education), physical activity, medical problems (menarche, Menopause) and dietary intake. The standard Menopausal Rating Scale was used to analyze the severity of the symptoms.^[4] Phase III (follow-up and statistical analysis), follow up was done on day 15 for recording the compliance and for providing the next batch of flax seeds for next 15 days. At last follow up (1 month), again menopausal rating scale was recorded.

STATISTICAL ANALYSIS

All the data was summarized in the form of mean \pm SD & frequency (percentage). for the analysis of the frequency chi- square test was used. Pre and post data of flax seeds or placebo was analyzed by student t test. All the statistical analysis was done by using SPSS 20.

RESULT

At baseline both the groups were comparable on following parameters, age, income, occupation, education status and nutrient intake (Table 1). The comparison of menopausal symptoms at baseline in both the group was also not significantly different (Table 2).

In Group 1 (flex seeds), pre and post intervention data showed that hot flushes score was 2.20 \pm 0.89 in Pre intervention group and 1.55 \pm 0.69 in post intervention group and difference was statistically significant (p-value<0.01). The symptom of heart discomfort, joint and muscle complaints, sexual problems, sleeping disturbances, urinary complaints and physical and mental exhaustion was significantly different between Pre and Post intervention in flax seeds group.

In Group 2 (Placebo), pre and post intervention data showed that all the studied menopausal symptoms was insignificant p>0.05)

Comparison of group 1 and 2 after intervention showed that hot flushes mean value in Group 1 was, 1.55 \pm 0.69 and 2.15 \pm 0.88 in Group 2. Which was significantly different (p=0.02). Symptom of depression (p- 0.04) and physical and mental exhaustion (p- 0.03) was significantly different between both the groups. It means flax seeds also helpful in depression and physical activity and mental exhaustion. Heart discomfort, joint and muscle complaints,

sexual problem urinary complaints, vaginal dryness, irritation and anxiety were insignificantly different between both the groups.

Table 1: Baseline data of both groups.

Parameters	Group 1(n=20)	Group 2(n=20)	p-value
Age (yrs): 45-50/ 51-55/ 56- 60	14(70)/ 5(25)/ 1(5)	12(60)/ 6(30)/ 2(10)	0.30
Educational status: illiterate/higher secondary/ graduation/ post graduation	1(5)/ 6(30)/ 6(30)/ 7(35)	2(10)/ 5(25)/ 7(35)/ 6(30)	0.89
Occupation housemaid/ working	11(55)/ 9(45)	14(70)/ 6(30)	0.17
Income <30K/ 30K-60K/ 60K-1 Lacs/> 1 Lacs	2(10)/ 8(40)/ 6(30)/4(20)	3(15)/ 8(40)/ 7(35)/ 2(10)	0.16
Energy	1763.10±260.69	1724.20±292	0.66
Protein	43.48±8.35	45.80±9	0.40
Fat	46.45±12.76	53.57±11.93	0.80
Calcium	605.96±172.24	644±172.73	0.49
Iron	15.33±2.87	15.02±2.55	0.72
Vitamin C	74.89±60.41	67.17±57.67	0.27

Data of Age, educational status, occupation, and income is presented as frequency and percentages in parenthesis.

Data of dietary intake is Mean ± SD

Table 2: Comparison of Menopausal symptoms of both groups- before and after intervention.

Symptoms	Groups	Pre intervention	Post intervention	p-value (Group 1 and 2 Pre)	p-value (Group 1 and 2 Post)	p-value (Group 1 Pre-post)	p-value (Group 2 Pre-post)
Hot flushes	Group 1	2.20±0.89	1.55±0.69	1	0.02	<0.01	0.14
	Group 2	2.20±.83	2.15±0.88				
Heart discomfort	Group 1	1.70±0.80	1.50±0.69	0.84	0.46	0.04	0.33
	Group 2	1.75±0.72	1.65±0.59				
Sleeping disorder	Group 1	2.10±0.79	1.55±0.94	0.10	0.01	0.01	0.16
	Group 2	2.45±0.51	2.25±0.64				
Joint and Muscle complaint	Group 1	1.80±0.83	1.60±0.75	0.40	0.08	0.04	1
	Group 2	2±0.65	2.25±0.65				
Sexual problems	Group 1	1.70±1.08	1.40±0.99	0.88	0.44	0.03	0.42
	Group 2	1.75±0.97	1.65±1.04				
Urinary complaints	Group 1	2.25±0.72	1.50±0.61	0.21	0.24	<0.01	0.2
	Group 2	1.95±0.76	1.75±0.72				
Vaginal dryness	Group 1	1.6±_0.82	1.35±0.67	0.84	0.41	0.10	1
	Group 2	1.55±0.69	1.55±0.83				
Depression	Group 1	1.65+_0.99	1.55±0.83	0.06	0.04	0.33	0.42
	Group 2	1.95±0.77	2.10±0.79				
Irritation	Group 1	2.30±0.86	2.15±0.88	0.86	0.872	0.08	0.33
	Group 2	2.35±0.88	2.25±0.91				
Anxiety	Group 1	2.55±1.05	2.25±1.02	0.86	0.872	0.08	0.26
	Group 2	2.50±0.69	2.30±0.92				
Physical & Mental exhaustion	Group 1	2.30±0.66	1.65±0.75	0.59	0.03	<0.01	0.96
	Group 2	2.4±0.50	2.15±0.67				

Data presented as Mean± SD

DISCUSSION

Menopause is a natural biological process; it marks the permanent end of fertility. The symptoms and signs of menopause generally appear well before that one-year period is over. Present study included Menstruation rating scale (MRS) for analyzing the menopausal symptoms.

The general demographic data revealed that out of 20 subjects in each group, 14 subject (70%) of Group 1 and 12 subject (60%) of Group 2 were in age group 45-50yrs. 5 subject(25%) of Group 1 and 6 subjects(30%) of Group 2 were in age group of 51-55yrs .1 subject (5%) of Group 1 and 2 subjects (10%) of Group 2 were in >55 yrs category, which was insignificant and also confirm that both the group were comparable on the parameter of age. Polite et al,(2004)^[5] on a representative sample of 495 Singaporean migrant women aged 40-60 showed that the mean age of participants was 49 years and the classical symptoms found were hot flushes (17.6%) vagina dryness (20.7%) and night sweat (8.9%). The most prevalent symptoms reported was low backache with aching muscle joints(51.4%). Nutrient intake of flax seeds (Group 1) and placebo (Group 2) was also similar.

The result showed that hot flushes, heart discomfort, joint and muscle complaints, and physical and mental exhaustion was very common in study subjects which also reported by Aaron et al (2003)^[6], while studying the 100 post menopausal and 100 perimenopausal rural women in south India. The study concludes that there was significant association between multiple somatic symptoms, vasomotor symptoms, urge incontinence, loss of sexual in menopause.

At baseline both the groups were comparable on following parameters, age, income, occupation, education status and nutrient intake. The comparison of all studied menopausal symptoms at baseline in both the group was also not significantly different, which showed that both the groups were comparable or similar at the starting point.

In Group 1 (flex seeds), pre and post intervention data showed that hot flushes score was 2.20 ± 0.89 in Pre intervention group and 1.55 ± 0.69 in post intervention group and difference was statistically significant (p -value <0.01). The intake of flax seeds reduces the symptoms of hot flushes in menopausal subjects. The study of preliminary data suggests that flax seeds, a rich source of dietary lignans, may be potentially effective treatment for hot flushes. A phase third randomized placebo controlled trial was conducted to evaluate the efficiency of flax

seeds introducing hot flashes. The results of this trial do not support the use of 410 mg of lignans for the reduction of hot flashes.^[7] The bars were fairly well tolerated, with both groups reporting gastrointestinal effects, likely due to the fiber content.^[5,6] The symptom of heart discomfort, joint and muscle complaints, sexual problems, sleeping disturbances, urinary complaints and physical and mental exhaustion was significantly different between Pre and Post intervention in flax seeds group. A study was conducted by Andreana et al^[8], showed that flax seeds are considered one of the richest sources of lignan phytoestrogen, several studies have developed technique to identify and quantify phytoestrogens in flax seeds. In a randomized cross trial of 3 weeks periods with flax seeds lignan, there was a reduction in LDL cholesterol, total cholesterol and no effect on HDL cholesterol. A 12 week study of 145 women with climacteric or menopausal complaints showed a reduction in menopausal symptoms (including hot flush and vaginal dryness) with consumption of a diet rich in phytoestrogens including soyabean foods and flax seeds.^[8]

After intervention of flax seeds at last follow up data showed that hot flushes was significantly different ($p=0.02$). Symptom of depression ($p= 0.04$) and physical and mental exhaustion ($p= 0.03$) was also significantly different between both the groups. It means flax seeds are helpful in hot flushes depression and physical activity and mental exhaustion. Heart discomfort, joint and muscle complaints, sexual problem urinary complaints, vaginal dryness, irritation and anxiety were insignificantly different between both the groups.

Present study had several limitations, like it had small sample size along with the follow up of short duration (only 1 month), longitudinal studies with larger sample sizes are required to establish the association of menopausal symptoms with flax seeds.

CONCLUSION

The study result revealed that the effect of flax seeds in (pre and post data) on menopausal symptoms was significant. The p - value of some of the symptom like hot flushes, heart discomfort, sleeping disturbances, joint and muscle complaints and urinary complaints are significant ($p<0.05$). The result revealed that symptoms like anxiety, depression, irritation and vaginal dryness were insignificant ($p>0.05$). The result of post data of flax seeds and placebo was revealed the significant difference in hot flushes, sleep disturbance, depression and Physical and mental exhaustion. The conclusion of study is that the flax seeds are beneficial for menopausal symptoms Flax seeds as mix with flour or in the form of seeds should be introduced in India through various health and nutrition schemes launched in India.

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