

**NUTRITIONAL STATUS OF PRE AND POST-MENOPAUSAL
WOMEN OF VADODARA.
METABOLIC AND INFLAMMATORY RESPONSE
TO SUPPLEMENTATION
OF WHOLE ROASTED FLAXSEEDS
IN PRE-MENOPAUSAL
OVERWEIGHT/OBESE
FEMALE SUBJECTS**

SUMMARY OF DOCTORAL RESEARCH (1000 words)

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Guide

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Summary

The prevalence of morbidity and mortality among women due to non-communicable diseases has been on rise in the last few decades. The major underlying causes of these diseases have been identified as physical inactivity, unhealthy diet, tobacco and alcohol consumption. Apart from these four factors menopause is a unique risk factor among women which can affect their endocrinology and body composition, making postmenopausal women predisposed to various non communicable diseases. Major upcoming metabolic risk factors for NCDs among women are vitamin B12 and folic acid deficiency, inflammation and insulin resistance. The prevalence of these metabolic factors among women and their association with other risk factors can provide a better insight for development of preventive strategies of non-communicable diseases. Incorporation of different functional foods like flaxseeds in the diet can be an effective approach towards promotion of healthy dietary habits among women. Flaxseeds are rich in α linolenic acid, lignans, different polyphenols and fiber. Regular incorporation of low doses of flaxseeds in the diet of apparently healthy overweight/obese pre-menopausal women as an early strategy to prevent development of non-communicable diseases, can lead to improvement in lipemic profile, high blood pressure, inflammation and insulin resistance in women.

Thus the present study was planned with the following major objectives:

1. To compare the life style, behavioural, dietary difference, if any, along with physiological and metabolic aberrations in pre and post-menopausal women
2. To explore the relationship of Vitamin B12, Folic acid deficiency, inflammation and insulin resistance with risk factors of non-communicable diseases among women
3. To study the efficacy of two different doses of whole roasted flaxseeds on lipid profile and inflammatory markers of pre-menopausal overweight or obese female subjects

The study was divided into three phases. First phase consisted of a cross sectional study in which detailed non-invasive risk analysis for NCDs was performed on 131 women of urban Vadodara. Further biochemical estimations were performed on 90

women in terms of lipid and glycemic profile, nutritional anemia, HsCRP, thyroid, liver and kidney function tests.

The results of first phase revealed negligible number of women consumed tobacco (0.8%) or alcohol (0%). About 70% of the subjects were moderately physically active. No significant difference between nutrient intake of pre and post-menopausal women was observed. The prevalence of overweight/obesity (74.8%) and hypertension (42%) was high among the subjects. The prevalence of high TC, high LDL-C levels, low HDL-C levels, hypertriglyceridemia, high HsCRP levels and insulin resistance was 45.6%, 72.2%, 28.9%, 12.2% 64% and 21.5% respectively. Around 12% of the subjects were found to be diabetic. Through logistic regression analysis menopause was found to be independently associated with body fat percent irrespective of age and obesity status of women. The prevalence of vitamin B12 and folic acid deficiency was 71% and 5.5% respectively. Two key causal factors identified through multivariate analysis for vitamin B12 deficiency were: Very low dietary intake of vitamin B12 ($<0.3\mu\text{g}/\text{day}$) and no regular health check-up. Vitamin B12 deficiency emerged as independent predictor for development of hypertension among women after adjustment for age and BMI using logistic regression. Metabolic Syndrome was found to be the key variable associated with Hs-CRP. The major determinants of insulin resistance predicted through logistic regression model were low HDL-C, high BMI and high energy intake in women.

To conclude, a trend of higher prevalence of anthropometric and metabolic aberrations was seen in both pre and post-menopausal women. Therefore a healthy life-style should be focused from the early stages of life with extra caution during and post menopause. Menopause can indirectly affect risk of cardio vascular disease through these fat distribution changes. The prevalence of vitamin B12 deficiency was found quite high and was found to be strongly associated with hypertension. These areas need to be further explored. HsCRP can be used as suggestive tool while assessing metabolic syndrome as well as diabetes and CVD risk in women.

In phase two, PKV-NL 260 variety of the flaxseed was selected to use for the supplementation and nutrient profiling was done. The fatty acid profile showed the highest percent (78.04%) of n-3 fatty acid in the PKV NL-260 variety of flaxseeds.

Phase three of the study was an open labelled randomized control trial. It included an initial screening of the women using inclusion and exclusion criteria. 90 subjects out of those who were eligible and consented to participate were randomly selected and divided into three groups. Biochemical estimations, anthropometric and biophysical assessment were performed pre and post supplementation. Biochemical estimation included lipid profile, fasting blood glucose, insulin, HsCRP, haematological profile, liver and kidney function tests. Experimental group I was asked to consume 5g of roasted flaxseeds and group II was asked to consume 10g of roasted flaxseeds for a period of 8 weeks. The control group was advised not to consume flaxseeds during the study period. 5g of flaxseeds contained 1.17g of ALA whereas 10g of flaxseed contained 2.34g of ALA.

The results of phase three indicated that no significant difference in the mean values of lipid profile was observed in the two supplementation groups (5g and 10g) post supplementation. Both 5g and 10g flaxseed supplementation brought better impact on the lipid profile of the subjects with initially high levels of LDL-C or AIP, though not statistically significant. Insulin ($p<0.05$) and HOMA IR ($p<0.05$) levels significantly decreased and % insulin sensitivity ($p<0.05$) significantly increased in subject with high HOMA IR levels (>1.2) post 10g flaxseed supplementation. Mean body fat percent ($p<0.01$) and SBP ($p<0.01$) levels significantly reduced in 5g flaxseed group post supplementation. Prevalence of pre/stage I hypertension significantly reduced in both 5g ($p<0.05$) and 10g ($p<0.05$) supplementation group.

Thus, flaxseeds exerted beneficial impact on blood pressure, insulin resistance (in subjects with HOMA IR >1.2) and body fat percent (5g flaxseed group), maintained lipid profile, anthropometric indices and failed to alter inflammation in the healthy overweight/obese subjects. Therefore hassle free strategies like inclusion of 5-10g of roasted flaxseeds in the form of “mukhwas” in the daily diet can be adapted to reduce the risk of metabolic aberrations in population.