CHAPTER- 3

METHODOLOGY
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STUDY DESIGN

CROSS SECTIONAL STUDY
- Purposive sampling N=750 women
  - General Information
  - Health Status
  - Menstrual Assessment
  - Nutritional Assessment
  - Assessment of Anxiety and Depression

SEMILONGITUDINAL STUDY - Interventional Study
- Purposive sampling 3 Months Intervention
  - Flax Seed Intervention n=10 women
  - Menopause Intervention n=10 women
  - Pre and Post Intervention
    - Blood Parameters: Lipid profile, Hb%, Ferritin, Hormones - Estrogen and progesterone
    - Menopause symptoms (Greene climacterics scale)
    - Quality of Life (QOL)
Menopause is a distressful period in woman’s life and every woman experiences this phase. The pattern of menopausal onset is characteristic to population. More than 80% of women experience physical and psychological symptoms in the year approaching menopause with various distress and distribution in their lives. [134-135]. The associated factors like food and nutrient intake and their influence on experiences of woman are important aspects of investigation. The present investigation was proposed to identify the age of onset of menopause, symptoms and other related individual and environmental factors affecting menopause. The methodological details are presented under the following heads.

1. Study Population
2. Development of Tools
3. Description of Tools Used in the Study
4. Conducting the Study
5. Data Management and Statistical Analysis

1. Study Population: The study population comprised of women aged between 35 to 55 years. The subjects of the study were selected from the women who were attendants to the patients in the Out Patient Clinic. The subjects were contacted during the year August 2009 to August 2011 and they were explained about the purpose of the study. The woman who were willing to participate out of their freewill were given the consent letter and requested to read the content carefully and sign the acceptance letter only if they consented to participate. Those women who voluntarily sign the consent letter were considered as subjects of the study. The selected women were from urban and semi urban areas of Dharwad city, Karnataka.
**Inclusion Criteria:** Women aged between 35-55 years having normal and overweight (BMI<32) without having renal and CVD problems.

**Exclusion Criteria:** Obese women (BMI >32), those who have undergone hysterectomy, on medication except for diabetes and other hormonal imbalances and ovarian problems.

**IHEC Approval:** The study was presented before the IHEC, University of Mysore, and Mysore. The approval was obtained before commencement of the data collection (copy enclosed in Appendix-F).

The approval was also obtained from the Institutional Ethical Committee, S.D.M. College of Medical Sciences and Hospital, Dharwad.

2. **Development of Tools**

The aspects proposed to investigate were assessed using appropriate questionnaires. The questionnaires were constructed for the purpose and standardized. Details of the various tools used in the present study are enlisted here with.

a. Demographic Information

b. Health Status

c. Menstrual Details and Menopause Symptoms

d. Nutritional Assessment

e. Assessment of Anxiety and Depression

f. Greene’s Climacteric Scale (Used for intervention study)

g. Quality of Life Scale- WHOQOL-BREF(Used for intervention study)

3. **Description of Tools:**

a. The questionnaire was developed to elicit general information about name, age, education, occupation, maternal history, family size, family type and husband’s
occupation, details about the type of house in which the subjects resided. Details about household equipment in possession, ownership of property was obtained in order to assess their SES.

b. Queries related to health condition including prevalence of metabolic and degenerative disease was elicited.

c. Menstrual history included queries regarding menstrual cycle and bleeding pattern. The bleeding pattern was assessed with the use of visual signs of the spot on the pad to indicate ‘Mild’, ‘Moderate’ and ‘Heavy bleeding’ and also number of days of flow was obtained.

Menopausal Symptoms: A close end assessment schedule was used to obtain symptoms of menopause which included gum problems, oral cavity problems, digestive changes, bone problems, muscle control changes, neurological problems, cardiovascular problems and other physiological symptoms. This was reproduced from [136].


(ii) Dietary Assessment-This was a detailed information about frequency of food intake, diet behavior, 24 hr recall for food and nutrient intakes.

(iii) Knowledge regarding special foods taken during menopause.

e. Standard questionnaire was used to measure anxiety and depression using HADS Scale [137]. This scale was assessed on 4 point scale with ‘0’ indicating ‘not at all’ to score ‘3’ indicating ‘definitely’. The questionnaire has 14 items covering various aspects of anxiety and depression including seven items in each subscale. The scoring and grading pattern is presented in Appendix-B. This questionnaire was selected based on its popularity for screening emotional disorder in patients in
hospital. This is a simple scale with high reproducibility and reliability. The other advantage of this scale is, it required short time for assessment.

f. Greene Climacteric Scale: Literature has provided references for assessing climacteric symptoms. Greene’s Climacteric Scale was developed for U.K. population. He identified 3 symptom clusters and labeled them as Psychological, Somatic and Vasomotor Symptoms. This is modified by Ritu Chattha et.al.,[138] to suit Indian women. This is on 4 point scale with scores as follows.

‘0’ indicating ‘Not at all’
‘1’ ‘Little’
‘2’ ‘Quite a bit’
‘3’ Extreme

Reliability of the modified scale was 0.83 and Cronbochs alpha 0.91 suggesting its suitability to Indian women population. Questionnaire is given Appendix-C.

g. WHO-QOL- This was adopted to obtain Quality of Life in the study population.

The scale was considered suitable for Indian population because the scale was developed based on 15 international cross cultural center assessments conducted simultaneously including India also as a center for assessment. The scale included four domains. They are **Domain 1-Physical, Domain 2- Psychological, Domain 3- Social relationships and Domain 4- Environment.** Each domain was scored using scales at a positive direction i.e. higher score indicating higher quality of life. Mean score of items within each domain is used to calculate domain scores and sum of all the domains is used to score total quality of life. Questionnaire is given in Appendix-D.
Conducting the Study: The present investigation is a prospective study conducted in two assessment periods.

I. Cross sectional study

II. Semi longitudinal study

I. Cross Sectional Study: This was the initial phase of the study where the subjects were contacted and requested to participate. The entire assessment protocols presented under description of tools were employed to obtain data from each selected subject. Anthropometric assessments were done using standards techniques. Jelliffe descriptions were adopted.

Anthropometric Assessment: The subjects from cross sectional study were measured for body weight, height, waist and hip circumferences. The techniques adopted were according to Jelliffie [139].

Height Measurement: A portable height measuring rod with an accuracy of 0.1cms was used to measure height.

Weight Measurement: A battery operated digital balance (Glan Electronic personal scale) was used to record the weight of the subjects.

Waist and Hip Circumferences: A fibre glass tape was used to measure the circumferences. Cut of levels used to indicate weight status were according to southeast population [140-141].

Dietary Intake: 24 hr recall was done for one day for each selected subject. Standard cups and other measurements were used as display items to quantify the intakes. The subjects were helped to remember food items consumed other than the regular meal used. Nutrient intake was computed using a ready recknor (Appendix-E) for cooked foods standardized for the purpose [142] and it was compared using RDA of ICMR 2010 [143].
Development of SES: The SES score was developed suitably for the study population. Items considered were occupation, education, house rental property, household articles. Occupation was given 0-5 scores (0-Unemployed, 1- Self Employee, 2- Labour, Housewives, 3- Agriculture and Business, 4- Private Employee, 5- Govt. Employee). Education was scored 0-4 (0- Illiterate, 1-Primary, 2- Secondary, 3- PUC, 4-Graduate) house type was scored (0-mud, 1-Tiled, 3-RCC) own and rented house scored as 1-2 (1-Rent, 2-Own) property as 1-2 (1- House, 2-Shop) Household articles were scored 1-3 indicating number of household articles. Therefore the total score was obtained as the ‘3’ and the least ‘20’ as highest. The scores were classified into 3 SES i.e. <8, 9-13 and > 14. They were labeled as

- Low SES (<8)
- Middle SES (9-13)
- High (>14)

Classification of Menopause Symptoms: A need was felt to classify menopause symptoms systematically so as to have a scale to identify the onset of menopause in women. Hence an arbitrary cut off levels were derived based on the highest frequency of occurrence of symptoms. Highest occurring symptom had a wide gap varying from 41 to 59%. Therefore 40% was considered as cutoff, based on the frequency, they were grouped as Constant symptoms occurring more than 40%, Usual symptoms more than 20%, Occasional symptoms more than 10% and Other symptoms less than 10%.

II. Semi longitudinal Study Included: Intervention programme which was continued for 3 months. It was proposed to have two supplements. One was flax seed because of its phytoestrogen content lignan and the second is a pharmacological preparation which is specially used as medical supplement to women. They were considered as independent groups.
**Assessment protocols:** The study was a self controlled study with pre and post assessment. The details of the assessment included the preliminary information collected during cross-sectional study forms the information for intervention. Additional assessment for intervention study were

   
   Hb% - By photoelectric colorimeter method.
   
   Ferritin – By CLIA Kit method
   
   Hormones- (oestrogen & progesterone) – Roche chemical kit method

2. Pre and post assessment of climacteric symptoms using Greene’s Climacteric Scale

3. Pre and post assessment of Quality of Life using WHOQOL-BREF scale.

**Preparation of the Supplement:** The supplement was given in the form of powder mildly spiced to imitate the spice adjunct (chutney powder). The flax seeds were roasted on a low flame for 7-8 min. with constant stirring to prevent overheating it was spread on a cloth for cooling. Spices were mixed in the following ratio. For 100 gms of flax seeds 10 gms of red chilli powder and 0.5 gm. of salt was added. They were powdered in grinder.

**Distribution of Supplement:** The prepared flax seed chutney powder was portioned for each day supplement containing 16.5 gms of flaxseed mixture. This contained 15 gms of flax seeds. The women on flax seed supplement were instructed to use the content as one or two equal parts in the day’s meal. Each woman provided the supplements for 10 days. Therefore the women visited the hospital to obtain the supplement once in 10 days. Each woman was contacted through telephone to ensure the intake of supplement.
Menopace- Menopace tablet were provided free of cost to all women in the supplementation group. Each woman was given 10 tablets and therefore every 10th day women visited the hospital to collect the supplement.

The first and 1st day of intervention programme were the days for assessment of blood parameters. Each subject underwent all the assessment protocols on the first and last day of intervention.

Data management and Statistical Analysis

The data obtained was carefully maintained, all the records of individual subjects were made into data sheet for easy access of information of each subject. The data was tabulated to draw meaningful inferences. Descriptive analysis was used to derive means, percentages, the means were compared using paired ‘t’ test and Pearson correlation test and analysis of variance was used. Chi square was applied to describe the relation and significance among the variables of the study. Principal component analysis was done to describe the association of variables.