Chapter III

RESEARCH METHODOLOGY

Research methodology indicates the systematic organisation of the procedure for gathering valid data about the topic of investigation. The methodology explains the various steps which are adopted by the researcher in studying the research problem. The steps, in methodology, includes the research approach, research design, research setting, study population, sampling technique, development and description of data collection instruments, development of the intervention, pilot study, procedure for data collection, and plan for data analysis.

Research Approach

The study was planned in two phases. The quantitative approach was used for the study to identify the menopausal problems and evaluate the effectiveness of multimodal intervention to minimize the menopausal problems.

Research Design

Phase I: A descriptive cross sectional survey was adopted for phase I. The aim of the descriptive cross sectional survey was to describe the existing relationship among the variables rather than to infer cause and effect relationship. In Phase I, the researcher identified the common menopausal problems, intensity of the menopausal problems and association between the
common menopausal problems with selected demographic and clinical variables of the midlife women.

**Phase II:** A true experimental - Factorial design with two interventions control group comparison was adopted to assess the effectiveness of multimodal intervention and EPCI on prevention and management of menopausal problems and coping ability of the midlife among the groups.

**Polit and Beck (2012)** explained that in factorial design, two or more independent variables or factors are manipulated simultaneously to observe the effects on the dependent variables. In factorial experiment the subjects are assigned to a specific combination or conditions. This design permits the researcher to test not only the main effects of interventions but also interaction effects from combining the interventions.

In this study, three groups were used. The group I received multimodal intervention. Group II received Exercise and Problem based Counseling Intervention (EPCI) by demonstration as well as video teaching. The control group received routine care. Menopausal problems were assessed with Lothar AJ. Heinemann Modified Menopausal Rating Scale; and coping ability was assessed with Modified C.S Carver BREIF Questionnaire at first and third month for all the three groups.

**Research Setting**

The study was conducted at C. Kothangudi Panchayath, Chidambaram. The C. Kothangudi Panchayath consists of 9 villages
and total population is nearly 2684. The setting for this study, phase I and phase II included all 9 villages of C. Kothangudi panchayath. It is located in Chidambaram and it comes under Parangipettai panchayath union (New Port in Portuguese) in Cuddalore district in the Indian state of Tamil Nadu. It’s a village panchayath union, located on the north back of Vellar River at a distance of 30 kms from Cuddalore and 250 kms away from the capital city of Chennai. C. Kothangudi panchayath has evolved into a well developed village panchayath with nearly all basic necessities such as health care, education and transport. Each village consists of minimum three to maximum seven streets and total number of streets in that panchayath is around forty.

According to Census of India (2011) the total population of C. Kothangudi panchayath was 2684. The male population was 1378, female population was 1306. Among the female population, 723 were in the age group of 21 to 44 years, 328 midlife women were in the age group of 45 to 60 years, and the geriatric (above 60) population was around 255. Most of them (79%) were from low socio economic status and their awareness towards health and health problems was inadequate. So inculcating the interest towards their self health is playing a greater challenge to the health care persons.

**Ethical Consideration**

Ethical clearance was obtained from the Institutional Human Ethical Committee of Rajah Muthiah Institute of Health Sciences for
conducting the study. The permission was also obtained from the president from C. Kothankudi Panchayath to conduct the study. Participants were informed about the study and written consent was obtained from each participant.

**Population**

**Target population**

The target population of the study was all Midlife women who were in the age of 45 to 60 years.

**Accessible population**

The accessible population was the midlife women who were between the age group of 45-60 years living in any villages of C. Kothangudi panchayath.

**Sample**

In this study, the samples were Midlife women, aged 45-60 years, who fulfilled the inclusion criteria and who were residing at C.Kothangudi panchayath.

**Criteria for Sample Selection**

**Phase I**

**Inclusion criteria**

- Midlife women who were between the age group of 45-60 years.
- Midlife women who were willing to participate in the study.
- Midlife women who knew to speak Tamil.

**Exclusion criteria**

- Midlife women who underwent hysterectomy and bilateral oophrectomy.
Midlife women who were receiving hormonal therapy.
Midlife women who were under oral contraceptive pills.
Midlife women having any chronic illness like diabetes mellitus, cardio vascular disease and hypertension.

**Phase II**

**Inclusion criteria**
- Midlife women who had the common menopausal problems
- Midlife women who were willing to participate in the study

**Exclusion criteria**
- Midlife women who were allergic to soy, peanut, or any other legume
- Midlife women who were doing regular exercises.
- Midlife women who had very severe level of menopausal problems
- Midlife women who were under hormonal treatment
- Midlife women who had breast cancer, hypotension, hypertension and thyroid disease.

**Sampling Technique and Sample Size**

Multistage sampling technique was used for the study. The setting of C. Kothangudi panchayath was selected by simple random sampling technique. Purposive sampling technique was used to select the samples for phase I. From the voters list out of 328 midlife women 275 midlife women who fulfilled the inclusion criteria were selected as samples for phase I. Based on inclusion criteria, around 153 samples of midlife women with mild, moderate and severe menopausal problems were selected for phase II from
phase I sample frame. Then the randomization was done by allocating the samples to different groups by adopting simple random sampling technique – lottery method. For each group 51 samples were allocated randomly.

Sample size

Phase I : 275 midlife women with menopausal problems

Phase II : 153 midlife women with menopausal problems who met the inclusion criteria were selected as samples and randomly assigned to the groups.

Sample Size Calculation

Based on the pilot study results the sample size has been determined. The following eight problems were identified as most common problems. They were hot flashes, joint pain, lack of energy, leg pain, mood swings, difficulty in falling asleep, dribbling of urine and vaginal dryness. Among these mood swing is the most significant problem. Out of fifty midlife women, thirty seven were having the symptoms of mood swing.

Keeping this as prior information, sample size has been determined using ‘N’ master sample size determination software with precision of 10% and level of confidence as 95%, required sample size has been 261. Assuming 5% non-response error, samples of 275 midlife women are selected in the study. So the total sample size was 275.

\[ n = \frac{Z^2 \alpha}{(EP)^2} \]
Sample Size

For phase I, a total of 275 midlife women, living in C.Kothankudi Panchayath were included. The phase–II sample size was 153 midlife women who fulfilled the phase II inclusion criteria were included from phase I sample frame.

Development and Description of the Data Collection Instrument

The most trustworthy evidence in evaluating the outcome of research investigation is through developing the appropriate tool to examine the study variables. Extensive literature search was done to find out the availability of any standardized tool to collect data for the study population. The researcher got few standardized instruments to collect data regarding menopausal problems, coping ability of midlife women after consultation with research experts from nursing, and medical profession. The tools were first developed in English and later translated into Tamil for data collection process. The final tool used for collection of data consisted of following sections for phase I and Phase II.

<table>
<thead>
<tr>
<th>Phase of Study</th>
<th>Part</th>
<th>Sections</th>
<th>Tool</th>
<th>No. of Items</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>I</td>
<td>A</td>
<td>Socio-demographic Proforma</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B</td>
<td>Clinical variable Proforma</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>II</td>
<td>C</td>
<td>Lothar A.J. Heninemann Modified Menopausal Rating Scale to Assess Menopausal Problems</td>
<td>38</td>
</tr>
</tbody>
</table>
Description of Data Collection Instrument

Part I

Section A: Socio Demographic Variable Proforma

The socio demographic variables of midlife women were collected by using a Proforma which consists of age, type of residence, marital status, education, occupation, and income of the subjects.

Section B: Clinical Variable Proforma

A clinical variable Proforma was prepared by the researcher. The variables were height, weight, BMI, stage of menopause, regularity of menstruation, recent changes in menstruation, weight gain, family planning method, remedial measures for menopausal problems, and any food allergy.

Part II

Section C: Modified Lothar AJ. Heinemann Menopausal Rating Scale

A five-point menopausal rating scale was modified by the researcher to assess the menopausal problems among the midlife
women. It consisted of 6 divisions such as physical problems, psychological problems, sleep problems, urinary problems, sexual problems and cardiac problems for assessing the menopausal problems.

Further, the physical problems were grouped as somatic problems, aches and pains. Psychological problems were categorized as mental exhaustion, depressive mood, and irritability and sleep problems, urogenital problems such as urinary and sexual problems.

**Score Interpretation**

For every mild symptom, score ‘1’ was given, for moderate symptoms score “2” was given, for severe symptoms score 3 was given, for very severe symptoms score 4 was given and for no symptoms 0 was given. The score ranges from minimum of ‘0’ to maximum of 144. Based on the total score obtained, the level of menopausal problems was classified as

<table>
<thead>
<tr>
<th>Score range</th>
<th>Level of menopausal symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Nil</td>
</tr>
<tr>
<td>1 – 38</td>
<td>Mild symptoms</td>
</tr>
<tr>
<td>39 – 76</td>
<td>Moderate symptoms</td>
</tr>
<tr>
<td>77 – 114</td>
<td>Severe symptoms</td>
</tr>
<tr>
<td>115 – 144</td>
<td>Very severe symptoms</td>
</tr>
</tbody>
</table>
Section D: Modified C.S Carver BREIF Questionnaire to assess the coping ability of midlife women

A modified five-point likert scale was used to assess the coping ability of the midlife women with menopausal problems. It consisted of 20 statements related to midlife women coping with menopausal problems. The response was tested as not at all / sometimes / always. Cronbach alpha test was applied to find out the internal consistency of the instrument ($\alpha = 0.8$). Further the coping ability were grouped as denial, disengagement, planning, seeking social support and religious coping.

Score Interpretation

Based on the total score obtained, the level of coping with menopausal problems was classified as:

<table>
<thead>
<tr>
<th>Score range</th>
<th>Level of coping</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 55</td>
<td>Mal adaptive coping</td>
</tr>
<tr>
<td>56 – 75</td>
<td>Adaptive coping</td>
</tr>
<tr>
<td>Above 75</td>
<td>Well adaptive coping</td>
</tr>
</tbody>
</table>

Part III

Section F: Bio chemical parameters

It consist of biochemical parameters such as FSH, ESTRADIOL, HDL, and LDL by laboratory methods.

Laboratory analysis of biochemical parameters was done by collecting 2ml of Fasting Blood samples to analyze FSH, ESTRADOIL, HDL, and LDL of midlife women.
Blood cholesterol (WHO, National Cholesterol Education Programme Classification, 2003)

<table>
<thead>
<tr>
<th>Blood cholesterol</th>
<th>Range</th>
<th>Classification</th>
<th>Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>HDL</td>
<td>&gt;55mg/dl</td>
<td>Desirable</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>35 - 55 mg/dl</td>
<td>Borderline</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>&lt;35 mg/dl</td>
<td>Highly</td>
<td>3</td>
</tr>
<tr>
<td>LDL</td>
<td>&lt;100mg/dl</td>
<td>Desirable</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>100 - 160 mg/dl</td>
<td>Borderline</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>&gt;160</td>
<td>High</td>
<td>3</td>
</tr>
<tr>
<td>FSH</td>
<td>&lt;50 IU/ml</td>
<td>Desirable</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>50 - 100IU/ml</td>
<td>Borderline</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>&gt;100IU/ml</td>
<td>High</td>
<td>3</td>
</tr>
<tr>
<td>ESTRADIOL</td>
<td>&gt;13pg/ml</td>
<td>Desirable</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>11 - 13 pg/ml</td>
<td>Borderline</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>&lt;10pg/ml</td>
<td>Highly declined</td>
<td>3</td>
</tr>
</tbody>
</table>

Description of the Intervention

The common menopausal problems were assessed by using menopausal rating scale in phase I. After collecting the data for phase I, those who met with the inclusion criteria for phase II was identified

Group-I: The intervention for group I was multimodal intervention consists of phytoestrogen diet therapy, general fitness and flexibility exercise and problem based counseling with the help of flash cards on prevention and management of menopausal problems. Phytoestrogen diet therapy consisting of 50 gms of dietary supplementation powder containing 45 mg of isoflavone.
**Preparation of grain mixture**: 100 gms of grains mixture consisting of soy 50 gms, peanut 25 gms, Dry Dates 25 gms was taken and it was washed with water, added with salt and it was dried under sunlight then it was roasted and it was prepared as fine powder.

The dietary supplementation powder was mixed with water and prepared as a laddus and it was administered under the supervision of the researcher and advised to eat every day morning, preferably after the breakfast up to 3 months. The cost of the laddu is Rs. 3.

**Exercise** denotes *general fitness and joint flexibility* exercise. It is simple and easy to perform. It has three combos, which are abdominal breathing and pelvic floor exercise, joint flexibility and muscle tension release and energy level increase. Exercise was demonstrator by the researcher every day evening for 30 minutes.

**Problem based counseling intervention** was given with the help of flash cards. The counseling includes standing instruction for management of somatic problems, aches and pains, psychological problems, sleep problems, genitor urinary problems, sexual problems and cardiac problems.

Follow-up of was done by the researcher up to three months.

**Group-II**: Received *general fitness and joint flexibility* exercise. It included deep abdominal breathing, pelvic floor
exercise, joint flexibility exercises, muscle tension free and energy level increasing exercise. It was demonstrated to the samples by video teaching method. It was taught to the samples every day evening for 30 minutes. Problem based counseling was administered along with the exercise. It was given to the samples followed by the pretest. Menopausal problems were assessed for each sample and the interventions for the particular problems were discussed once on the day of initiation of the intervention and follow-up was done by the researcher once in a week upto three months.

**Control group:** Received only routine care.

**Content Validity**

Eight experts scrutinized the data collection instruments. The expert team included 4 nursing professors from different specialties of nursing, three professors from Rajah Muthiah Medical College Hospital, and a Bio statistician. The suggestions given by the experts were incorporated in the final tool. The final instrument was translated into Tamil (local language) and the Tamil translation was retranslated into English for validity of the translated version. The translated instrument was found to be congruent with the original instrument.

**Pilot Study**

A pilot study was conducted from August 2013 to December 2013. It was carried out in two villages that were not included in
the main study. For first phase 50 samples who met with the inclusion criteria were selected by using purposive sampling technique. The purpose of the study was explained and informed-consent was obtained from each sample. The data were collected by using structured interview schedule. In Phase I, various dimensions of menopausal problems and their coping ability, were assessed among the midlife women. It took about 15-30 minutes after assessing their menopausal problems, and coping ability.

Among the participants those who met with the inclusion criteria were selected for phase II. For phase II around 15 samples were selected. And they were equally divided into three groups as control (five samples), group I (five samples) and group II (five samples). After the preliminary assessment, biophysiological parameters, was monitored from the all three group of samples before administering the intervention. The multi-modal intervention was administered to group I; EPCI was administered to group II. The intervention was administered for 3 months, followed by posttest was conducted.

Post assessment includes assessing the menopausal problems, coping ability and bio chemical parameters such as FSH, ESTRADIOL, HDL, and LDL. In second phase for each sample, each visit took 45 minutes to discuss and implement the intervention.

Based on the pilot study, few modifications were made in the data collection instrument, intervention, and data collection
procedure. The investigator did not encounter any practical difficulties, the study was found to be feasible. Hence the investigator decided to follow the same method for data collection of the main study. The modification made after the pilot study were,

- Consent form was modified according to the study.
- Few modifications were made in the modified menopausal rating scale in the physical and psychological aspects.
- Sample collection for bio chemical parameters was restricted to menopausal and post menopausal women.
- Exercise was planned to be administered in the evening.
- Data collection period was restricted to three months.

**Reliability**

The reliability of the tool was established by test – retest method. The reliability (r) correlation coefficient value was

- For modified Heinemann menopausal rating scale by test retest method r=0.97
- For modified Carver BREIF cope questionnaire by test - retest method r =0.78

**Data Collection Procedure**

The data collection process was done in two phases. In phase I, the midlife women suffering from menopausal problems were identified. Of the selected samples, those who met with the
inclusion criteria for the study were chosen and involved in phase II.

The data for both phase I and II were collected in the period between January 2014 and July 2015. It took around two years to collect the essential data required for the study. The researcher, before beginning the study, has obtained the permission from the president of C. Kothangudi Panchayath, Chidambaran by explaining the significance of the study.

**Phase I**

The data collection for phase I was done from January 2014 to June 2014. A descriptive cross-sectional survey approach was adopted for collecting the preliminary data for phase-I, using the purposive sampling technique.

A brief introduction and a detailed explanation about the study, its purpose and other related activities involved in the study were thoroughly discussed with the samples.

The consent was obtained from the samples and the confidentiality of their responses was assured. A total of 275 samples were identified, of which 6 to 7 midlife women were chosen as study subjects every day and for each women it took 5 to 10 minutes for establishing interpersonal relationship.

The study subjects were interviewed regarding the personal data and clinical variables, menopausal problems and remedial
measures adopted for menopausal problems. The data collection period for phase I was from January 2014 to October 2014.

**Phase I** ended with the selection of samples who expressed their interest and willingness to participate in the study, since every one them had one or other most common problems related to menopause.

**Phase II** from the phase I sample frame, a total of 153 samples, who met with inclusion criteria, were chosen for the phase II. By adopting the factorial design, the subjects were allocated randomly in control group, group I and group II by using simple random sampling – lottery method.

**Data Collection Period for the Groups**

- **Control group** - November 2014 to January 2015
- **Group II** - February 2015 to April 2015
- **Group I** - May 2015 to July 2015

The data were collected first from the control group, then from group II finally from group I to avoid contamination of the samples.

On the first day the researcher established the interpersonal relationship with the subjects, following which the researcher collected the demographic and the clinical data for all three groups.

For implementation of the interventions, six to seven houses from each group identified with the help of gram sabah members
and the president of C. Kothangui panchayath, on the samples were requested to assemble in those houses for performing the interventions, the researcher performed the interventions by visiting the individual houses, for samples those who hesitate to attend in a group.

The researcher collected 2ml of blood in the morning with six to eight hours of fasting, from the midlife women of three groups, those who were only in the stage of menopause and post menopause during the pretest and posttest for assessing the biochemical parameters such as FSH, Estradiol, HDL and LDL.

The actual initiation and implementation of the intervention by the researcher starts from the second day onwards.

**Control Group**

The researcher established the interpersonal relationship with the subjects, following which the researcher assessed the menopausal problems, and coping ability after that blood samples was collected from the subjects for biochemical analysis.

After a gap of three months a posttest was conducted for the same group to find whether any changes in the menopausal problems, coping ability and biochemical parameters found in the pretest.

After completing the initial study on the control with pre and posttest, the researcher moved on to study the group II and group I.


**Group II**

For group II, after doing the pretest assessment, the researcher administered the EPCI. The EPCI includes general fitness and flexibility exercises and counseling interventions. At this stage 6 to 7 houses were indicated as the venue for the exercises.

Every day, the researcher took 5 to 10 minutes to assemble and motivate the subjects to perform the exercises, appraised the samples of the benefits in performing these exercises and to alleviate had menopausal problems. After winning the confidence of the samples the researcher demonstrated the exercises personally as well as video pictures to the subjects everyday every day for 30 to 45 mts.

After the exercises, the samples were assessed for their mastery of exercises. The practice of exercises went on for 3 months and the researcher observed the developments or impact of the exercises on the samples once in a week. The researcher met the samples in their own houses who were hesitant in doing the exercises in a group.

In the evenings, a set of exercises comprising (general fitness such as deep abdominal breathing and pelvic floor exercises, joint flexibility exercises) were administered on the samples, besides the researcher has listened to the individual menopausal problems and problem based counseling was given using flash cards. The
implementation of the intervention and followup of the subjects while performing the intervention was done for three months. Then the posttest was conducted after 3 months among the study participants to estimates the changes occur in the menopausal problems, coping ability and biochemical parameters.

Once the data collection procedure is over for group II, the researcher continued the study with group I.

**Group I (Multimodal Intervention)**

The researcher, after winning the cooperation with the subjects, initially the demographic and clinical variables, menopausal problems, coping ability and biochemical parameters were measured.

After that initiation and implementation of the multimodal intervention (phytoestrogen diet therapy, joint flexibility, general fitness and flexibility exercise and individual problem based counseling) were administered on the samples of group I by giving them supplementation of (50 gms of phytoestrogen laddu) everyday morning. Under the supervision of the researcher preferably after the breakfast. In the evenings, a set of exercises comprising general fitness and flexibility exercises were administered on the samples for 30 to 45 minutes, besides the researcher has listened to the individual menopausal problems and problem based counseling was given using flash cards.
The implementation of the intervention (diet therapy exercise and counseling intervention) and followup of the samples during the intervention was done for 3 months. A posttest was conducted to assess the effect of intervention in reducing the menopausal problems, the improvement level in the coping ability and to find any significant changes in the bio-chemical parameters for which 2 ml of blood was collected from the samples.

During the data collection period one sample from control, group II and two samples from group I was dropped out from the study due to the personal problems. So the total samples participated in phase II became 149.

**Plan for Data Analysis**

The information collected in phase I and phase II from the samples was scored and tabulated. The data were entered into the master coding sheet and saved in EXCEL. Then, the data were analyzed using descriptive and inferential statistics.

**Descriptive Statistics**

- Frequency and percentage distribution was used to analyze the demographic and clinical variables, menopausal problems, coping ability.

- Mean and standard deviation was used to analyze the bio physiological parameters of midlife women during menopausal transition.
Inferential Statistics

- Chi-square analysis was used to assess the homogeneity of the samples of demographic and association of common menopausal problems with demographic and clinical variables.

- One way ANOVA and ANCOVA was used to evaluate the effectiveness of interventions on menopausal problems, coping ability and bio-physiology.

- The LSD multiple comparison test was used to compare the effectiveness of multimodal intervention on menopausal problems of midlife women with other interventions.

- Paired “t” test was used to compare the bio physiological parameters of the midlife women during the menopausal transition and to test the effectiveness of multimodal intervention and EPCI.