Chapter III

RESEARCH METHODOLOGY

Research methodology is the plan, structure and strategy of investigation conceived to obtain answers to research questions on problems. It includes an outline of what the investigator will do from writing the hypothesis and their operational implications to the final analysis of data and its implications. Thus, it is a procedural plan that is adopted by the researcher to answer questions validly, objectively and accurately (Kumar, 2004).

The steps in methodology include the research approach, research design, research setting, development and description of data collection instrument, pilot study procedure for data collection, and plan for data analysis.

Research Approach

The research approach serves as a basic procedure to conduct and proceed the study. The research approach guides the research to collect the nature of data and the method of collecting data and the type of statistical methods to be used. It also suggests possible conclusions to be drawn from the data. In view of the nature of the problem selected for the present study, and to accomplish the objectives of the study, quantitative approach was chosen as an appropriate research tool.
Research Design

The term research design refers to the plan of a scientific investigation. Research design helps the researcher in the selection of subjects, identification of variables, their manipulation and control, statistical analysis to interpret the data, and the overall plan for addressing a research question, including specifications for enhancing the integrity of the study (Polit and Hungler 2007). Quasi experimental design was selected in this study for phase-I and phase-II and it consists of three groups. This was presented schematically and followed by a detailed description of phases-I and phase II respectively.

Figure 2: Schematic Research Design of the Study

<table>
<thead>
<tr>
<th>Groups</th>
<th>Pretest</th>
<th>Intervention</th>
<th>Posttest after 15 days</th>
<th>Intervention</th>
<th>Posttest after 90 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1</td>
<td>O₁</td>
<td>X₁</td>
<td>O₂</td>
<td>X₂</td>
<td>O₃</td>
</tr>
<tr>
<td>E2</td>
<td>O₁</td>
<td>X₁</td>
<td>O₂</td>
<td>X₃</td>
<td>O₃</td>
</tr>
<tr>
<td>C</td>
<td>O₁</td>
<td>X₀</td>
<td>O₂</td>
<td>X₀</td>
<td>O₃</td>
</tr>
</tbody>
</table>

E1 - Experimental group -I
E2 - Experimental group-II
C - Control group
O₁ - Pretest assessment of subject’s Knowledge, attitude and practice, general physical examination and Hematological estimation on prevention of anemia.
X₁ - Intervention on structured teaching programme on prevention of anemia.

X₀ - No intervention

O₂ - Posttest assessment of subject’s Knowledge, attitude on prevention of anemia 15 days after (STP)

O₂ - For control group refer to posttest assessment of subjects: knowledge, attitude on prevention of anemia after 15 days without intervention.

X₂ - Supplementation of cooked drumstick leaves 100gm for 3 days per week for 90 days.

X₃ - Supplementation of cooked cauliflower leaves 100gm for 3 days per week for 90 days.

O₃ - Posttest assessment of practice, general physical examination and hematological variables for 90 days after the dietary supplementation.

**Research Setting**

The nursing department (RMCON) has adopted 6 villages namely in Chidambaram Taluk, South Pichavaram, Kanagarapattu, Pinathur, Chidambaranathan Pettai, Natarajapuram, and Kumaramangalam for their community field visit. Out of these villages, three villages namely South Pichavaram, Kumaramangalam and Kanagarapattu were randomly selected for the study. For the experimental group-I 65 subjects were selected from Pichavaram based on their Hb level. For the experimental group-II, 70 subjects were selected from Kumaramangalam village based on their Hb level and for the control group 60 subjects were selected from Kanagarapattu village located in
Parangipettai Panchayat Union in Chidambaram Taluk, Cuddalore District. The population details of the above village’s are as follows:

<table>
<thead>
<tr>
<th>Name of the villages</th>
<th>Total population</th>
<th>Male</th>
<th>Female</th>
<th>Women 15-45 years</th>
<th>Number of subject anemic 9-12g/dl</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pichavaram</td>
<td>910</td>
<td>452</td>
<td>448</td>
<td>227</td>
<td>65</td>
</tr>
<tr>
<td>Kumaramangalam</td>
<td>880</td>
<td>448</td>
<td>432</td>
<td>217</td>
<td>70</td>
</tr>
<tr>
<td>Kanagarapattu</td>
<td>1225</td>
<td>610</td>
<td>615</td>
<td>262</td>
<td>60</td>
</tr>
</tbody>
</table>

**Samples**

The sample respondents for the study were selected using purposive sampling technique. The sample consisted of married and unmarried women of reproductive age between 15-45 years who had their Hb level between 9-12 gm/dl having mild and moderate anemia. Those who had <9 gm% of Hb were not included as advised by the ethical committee as the subject having moderate and severe anemia needs intensive treatment.

**Sample Size**

The sample size consisted of 195 subjects in total out of which 65 were allotted to the experimental group-I, 70 were allotted to the experimental group-II and 60 to the control group.

**Criteria for Sample Selection**

**Inclusion Criteria**

1. Subjects belonging to reproductive age group between (15 - 45 years).
2. Subjects available at the time of data collection.
3. Subjects willing to give their blood for testing hemoglobin.

4. Subjects willing to participate in the study.

5. Subjects both married and unmarried

6. Subjects willing to consume cauliflower leaves and drumstick leaves for the specified period of time.

7. Subjects who can speak and understand Tamil

**Exclusion criteria**

1. Mentally ill Women

2. Subjects who are an treatment for anemia having moderate and severe anemia (i.e) Hb level less than 9 gm/dl.

3. Subjects who are pregnant.

**Variables under the Study**

The independent and dependent variables included in this study.

**Independent variables**

According to Polit and Hungler (2007), variable is believed to influence the behavior and ideas. In this study, the independent variables used were structured teaching programme and dietary supplementation of drumstick leaves poriyal for experimental group-I and cauliflower leaves poriyal for experimental II.
**Dependent variables**

The variables that the researcher is interested in understanding, explaining, and identifying the outcome of the study variables *(Polit and Hungler, 2007).*

In this study, the dependent variables refer to the knowledge, attitude and practice on prevention of anemia.

**Extraneous variables**

Extraneous variables are those variables that are present in research environment. This may interfere with research findings by acting as unwanted independent variables *(Woods and Kahn, 1994).*

In this study, extraneous variables refer to the selected socio-demographic variables such as age, educational status, income, marital status, religion, and occupational status. Previous knowledge on anemia, availability of various resources such as internet etc.

**Sampling Technique**

Purposive sampling technique was adopted for the selection of sample in both experimental groups and control group.

**Development of the Tool**

The researcher developed the tool based on the objectives of the study, after the extensive literature review using internet search, books, journals and other publication. The tool was
developed in Tamil and English for data collection. The final tool (Appendix No. VI) consisted of five sections as below:

**Section A**

The structured interview guide (Appendix No. VI) was considered to be the most efficient and objective method of deriving necessary information from the women of reproductive age group. This method was followed because direct questioning is appropriate in assessing the demographic data of the women of reproductive age group. It consisted of structured questions that assessed the age, education, occupation, income, type of family and source of information and gynecological and obstetrical variables such as age at marriage, age at first pregnancy, interval between each pregnancy, parity status, number of abortion and additional information about the dietary pattern.

**Section B**

This consists of 35 multiple choice questions (Appendix No. VI) related to knowledge on prevention of anemia. Questions from 1 to 7 were on basic concepts of reproductive health, questions from 8 to 14 were on meaning and causes of anemia, questions from 15 to 19 were on signs and symptoms, questions from 20 and 21 were on diagnosis of anemia, questions from 22 to 28 were on treatment, questions from 29 to 34 were on prevention and 1 question was on the complication of anemia.

The section consists of 35 multiple choice questions related to knowledge on anemia. Each correct answer was given a score of
“1” mark and the wrong answer was given a score of “0”, thus the total Score for correct answers was 35. Based on the total score obtained, the level of knowledge was classified.

The scores were categorized as follows:

<table>
<thead>
<tr>
<th>Level of knowledge</th>
<th>Range of score</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate knowledge</td>
<td>27-35</td>
<td>&gt;76%</td>
</tr>
<tr>
<td>Moderately adequate knowledge</td>
<td>18-26</td>
<td>51-75%</td>
</tr>
<tr>
<td>Inadequate knowledge</td>
<td>0-17</td>
<td>&lt;50%</td>
</tr>
</tbody>
</table>

Section C

An attitude scale (Appendix No. VI) was formed by the investigator based on 5 point likert scale consisting of 15 statements to find out the attitude regarding prevention of anemia. Out of the 15 statements, 7 statements were positive and 8 statements were negative.

The positive statement had a score of 5, 4, 3, 2, 1 and negative statements had an score of 1, 2, 3, 4, and 5 respectively. Based on the total score obtained were 43 and the level of attitude was classified as

<table>
<thead>
<tr>
<th>Level of attitude</th>
<th>Range of score</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most favorable attitude</td>
<td>32-43</td>
<td>&gt;76%</td>
</tr>
<tr>
<td>Favorable attitude</td>
<td>22-31</td>
<td>51-75%</td>
</tr>
<tr>
<td>Unfavorable attitude</td>
<td>0-21</td>
<td>&lt;50%</td>
</tr>
</tbody>
</table>
Section D

This is a questionnaire (Appendix No. VI) to assess the practice regarding prevention of anemia. This questionnaire was classified into 7 aspects related to prevention of anemia. Questions from 1-4 were related to cooking practices, questions from 5-7 were related to practice of good hygiene, questions from 8-19 were related to consumption of iron rich sources, questions from 20-25 were related to iron enhancer and iron inhibitors, and questions from 26-30 were related to awareness on prevention of anemia.

The practice questionnaire consisted of 30 questions. Observation checklist was prepared and each correct answer was given a score of one and wrong answer was scored as 0. The total practice score was interpreted as below.

<table>
<thead>
<tr>
<th>Level of Practice</th>
<th>Range of score</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate practice</td>
<td>23-30</td>
<td>&gt;76%</td>
</tr>
<tr>
<td>Moderately adequate practice</td>
<td>16-22</td>
<td>51-75 %</td>
</tr>
<tr>
<td>Inadequate practice</td>
<td>0-15</td>
<td>&lt;50%</td>
</tr>
</tbody>
</table>

Section E

Section E consisted of an assessment proforma (Appendix No. VI) used for physical assessment to identify anemia which includes information related to anthropometric measurements: height, weight and BMI. Clinical signs consisted of general appearance, eyes, tongue, lips, gums, paleness of nails beds and
clinical variables such as dyspnea, palpitation, fatigue, giddiness, pulse rate and respiratory rates were assessed for all the subjects.

These measurements are used to assess the physical development of the reproductive age group of woman.

**Height:** Height was measured with the help of non-stretch tape that was fixed to the flat wall. The respondents were asked to remain barefoot and the hair flat. Both feet were together with heels, buttocks, and shoulders touching the wall. The respondents were asked to stand erect looking straight ahead the top of the ear and the outer corner of the eye was in line parallel to the floor. The hands were hanging by the sides in a natural manner and a horizontal bar was allowed to rest flat on top of the head and height was recorded to the nearest 0.5 cm.

**Weight:** The weight of the subjects was measured with the help of weighing machine. The subjects were weighed with minimum of clothing. The subjects were weighed thrice and an average of the three readings was taken as the final measurement.

**Body Mass Index (BMI):** It is calculated by dividing weight in kg by the square of height in meters. The calculations were compared with standard for classification of the sample (*Sutra 2005*).

\[
\text{BMI} = \frac{\text{Weight (kg)}}{\text{Height (m}^2\text{)}}
\]
Since the height of respondents was recorded in centimeters, for the calculation, BMI height in centimeter was first converted into height in meters.

**Interpretation of Body Mass Index (BMI)**

<table>
<thead>
<tr>
<th>Based on BMI</th>
<th>Body Mass Index kg/m²</th>
<th>Health Risk association</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under weight</td>
<td>Below 18.5</td>
<td>Low</td>
</tr>
<tr>
<td>Normal range</td>
<td>18.5 – 25</td>
<td>Moderate</td>
</tr>
<tr>
<td>Over weight</td>
<td>25 – 30</td>
<td>High</td>
</tr>
<tr>
<td>Obesity</td>
<td>Above 30</td>
<td>Very high</td>
</tr>
</tbody>
</table>

**Clinical assessment**

Clinical examination is the most essential part of all nutrition surveys. The method is based on examination of the subject for changes, believed to be related to various nutrient deficiencies that can be seen or felt in superficial epithelial tissues especially eyes, tongue, gums, paleness of nail beds, etc. This section deals with the observing signs and symptoms on prevention of anemia.

**Assessment of hematological variables**

The Hemoglobin and hematological estimation was done for all the 195 samples in RMMCH in the clinical laboratory using cynmethaemoglobin method. The reading was compared with WHO standards for classification of anemic samples.
Classification of anemia

According to the WHO, anemia is classified as

<table>
<thead>
<tr>
<th>Severity of anemia</th>
<th>WHO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>12 - 9g/dl</td>
</tr>
<tr>
<td>Moderate</td>
<td>7 - &lt;9gm%</td>
</tr>
<tr>
<td>Severe</td>
<td>&lt;7g/dl</td>
</tr>
</tbody>
</table>

Hematological assessment and reference values

<table>
<thead>
<tr>
<th>Component</th>
<th>Normal range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hb (gm/dL)</td>
<td>12 - 14</td>
</tr>
<tr>
<td>RBC (x10⁶/µL)</td>
<td>3.5 – 5.0</td>
</tr>
<tr>
<td>HCT (%)</td>
<td>33 – 37</td>
</tr>
<tr>
<td>MCV (fL)</td>
<td>82 – 96</td>
</tr>
<tr>
<td>MCH (pg)</td>
<td>27 – 33</td>
</tr>
<tr>
<td>MCHC (gm/dL)</td>
<td>33 - 37</td>
</tr>
</tbody>
</table>

Content Validity

Content validity of the tool was obtained from eight experts in the field of Nursing and Medicine. The developed tool was given to 8 experts who scrutinized the data collection instruments. The experts’ team included 6 nursing professors and one physician from Rajah Muthiah Medical College and a Biostatistician. 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.

**Ethical Consideration**

Ethical clearance was obtained from the Institutional human Ethical committee at the Rajah Muthiah Institute of Health Science to conduct the study. The committee suggested to undergo pesticide analysis for the detection of residual pesticide on cauliflower leaves and to pursue the study thereafter. Accordingly pesticide analysis of cauliflower leaves was undertaken at (Tamil Nadu Agricultural University) Coimbatore. The detailed report was collected and the result found free of any pesticide residues. (The report included in the appendix 5). Based on the reports received, permission was received to administer the cauliflower leaves for the experimental group-II.

Institution permission was obtained from the Medical Superintendent, Rajah Muthiah Medical College and Hospital to use lab facilities to estimate the hemoglobin and hematological test. Permission was obtained from all the three (Pitchvaram, Kangarapattu and Kumaramanglam) village presidents to conduct the study. Written consent was obtained from the subjects. Data were collected for the main study between 2013 and 2014 for the three groups in the respective villages.
**Pilot Study**

A pilot study was undertaken before starting the major study. A pilot study was conducted from October 2012 to March 2013 at Omakulam, Chidambaram Taluk in an identical setting. The permission was obtained from the village President.

Ten subjects who met inclusion criteria were selected for each group 10 subjects were selected on the basis of purposive sampling for all the three groups: experimental group-I consisting of 10 subjects, experimental group-II consisting of 10 subjects and control group consisting of 10 subjects. Data were collected using structured interview guide. The selected subjects for the pilot study took up pretest for 4 days. It took about 15-20 minutes.

The posttest was conducted after 15 days, administrating the same Knowledge, attitude and practice questionnaire. After 90 days blood sample was taken and investigations were made.

The data collected were computed and analysed using inferential statistics. The finding of the pilot study concluded that the STP and dietary supplementation was effective to improve the knowledge, attitude and practice on anemia among women of reproductive age group.

**Reliability**

The reliability of the tool was established by Cronbach’s alpha method and it was found to be significant at r=0.72.
Description of the Intervention

Structured Teaching Programme

It is a well-prepared teaching programme with systematically developed information, along with visual aids designed to teach the women on prevention of anemia. It includes meaning of anemia causes, signs and symptoms, diagnosis, treatment, prevention and complication of iron deficiency anemia using flash card. The experimental group-I and experimental group-II were subjected to structured teaching programme on prevention and complication of anemia.

Deworming

Deworming is the giving of an antihelmintic drug to a human to rid them of helminthes parasites such as roundworm, hookworm and tapeworm. Deworming was done with tablet Albendazole 400mg, single dose for all the subjects in the experimental group–I, experimental–II, and control group.

Dietary supplementation

After the 16th day the dietary supplementation started for both the experimental group–I and experimental group–II. The experimental group–I received cooked drumstick leaves 100gm (poriyal) for 3 days per week for 3 months (90 days) and the experimental group–II received cooked cauliflower leaves 100 gm (poriyal) for 3 days per week for 3 months (90 days).
Data Collection Procedure

Data was collected from April 2013 to September 2013 for experimental group-I and control group. For the experimental group-II from October 2013 to March 2014. The researcher introduced herself to the subjects. The Data collection procedure was explained to the subjects saying that the data will be kept confidential and will be used only for research purpose. The subjects were told about the freedom of withdrawing from the study at any time and informed written consent was obtained.

Initially, the researcher conducted a pretest for all the three groups – control group, experimental groups I and II. The pretest scores helped the investigator to assess the knowledge level of the subjects about the prevention of anemia by using the structured interview guide. The five point Likert scale was used to assess the attitude level, and the observational check list was used to assess the practice of the subjects about the prevention of anemia. Deworming was done for all the subjects soon after pretest. A single dose of Albendazole 400mg single dose was administered.

Immediately after the pretest, a structured teaching programme was given to the experimental groups I and II using flash cards. But for the control group no structured teaching programme was given. A posttest was conducted on the 15th day for all the three group with the same questions tool to assess the knowledge and attitude.
The investigator started the intervention of dietary supplementation for the experimental groups I and II immediately after conducting the posttest.

After 90 days posttest was done for the control group without giving any intervention.

The investigator administered the dietary supplementation of 100 gm of cooked drumstick leaves (*Moringa oleifera*) in the form of poriyal to the subjects belonging to the experimental group-I, on namely Monday, Wednesday and Friday in the afternoon for three days a week for 90 days from April 2013 to September 2013. The scheduled is enclosed in (Appendix No. VII).

In the same way for the experimental group-II, the investigator administered a dietary supplementation of 100 gm of cooked cauliflower leaves for a period of 90 days from October 2013 to March 2014 for experimental group-I and experimental group-II in different villages. The dietary supplementation for this group was given for three days a week, on the alternative days, namely Tuesday, Thursday and Saturday. After 90 days posttest was conducted. The practice level was assessed after 90 days for all 3 groups using the same tool. General physical examination were done to assess the signs of anemia. Blood test was done to assess the haematological variables.
Statistical Method Applied for Data Analysis

Statistical analysis helps the researcher to make sense of quantitative information. Without statistics, quantitative data would be a chaotic mass of numbers. Statistical procedure enables researchers to summarize, organize, evaluate, interpret, and communicate numeric information (Polit and Denise, 2009).

Both descriptive and inferential statistics were used for analyzing the data. The descriptive statistics used were mean, standard deviation and percentage.

Inferential statistics such as chi-square, Paired ‘t’ test, Scheffe’s multiple comparison and Least Significant Difference (LSD) were also employed. One-way ANOVA was used to identify the relationship between the experimental group-I, experimental group-II and control group. ANCOVA was used to test the mean differences on outcome variables with the groups and with the co variables. For the entire statistical test, P<0.05 was considered the level of significance for further analysis.