CHAPTER-III

METHODOLOGY

The methodology of research indicates the general pattern of organizing the procedure of gathering valid and reliable data for the problem under investigations (Kothari, 1996).

The methodology of this study includes research approach, research design, variables, the setting, population, sample size, sampling technique, the inclusion and exclusion criteria, development and description of the tools, tool validity, reliability, pilot study, data collection procedure and plan for data analysis based on the statement of problem and objectives of the study.

3.1 Research approach & research design

Research design refers to a researcher’s overall plan for obtaining answers to the research questions and it spells out strategies that the researcher adopt to develop information that is adequate, accurate, objective and interpretable (Polit - 2001).

Randomized control trial with pre and post-test design and an evaluatory approach was used to assess the effectiveness of video assisted teaching module on contraceptive methods including emergency contraception with regard to knowledge, attitude and practice of couples.
Table 3.1: Schematic representation of Research Design

<table>
<thead>
<tr>
<th>Eligible couples</th>
<th>Pre-test knowledge, attitude and practice</th>
<th>Video assisted teaching module</th>
<th>Post-test knowledge, attitude and practice</th>
<th>Video assisted teaching module</th>
<th>Post-test knowledge, attitude and practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention group</td>
<td>O₁</td>
<td>X₁</td>
<td>O₂</td>
<td>X₂</td>
<td>O₃</td>
</tr>
<tr>
<td>Control group</td>
<td>O₁</td>
<td>-</td>
<td>O₂</td>
<td>-</td>
<td>O₃</td>
</tr>
</tbody>
</table>

O₁ - Pre-test knowledge, attitude and practice of the couples regarding contraceptive methods and Emergency Contraception of control and intervention group.

X₁ - Presentation of video assisted teaching module regarding contraceptive methods and emergency contraception to the intervention group.

O₂ - Post-test I Knowledge, attitude and practice of couples regarding contraceptive methods and emergency contraception of control group and intervention group (In 1 month for knowledge, 2 months for attitude, and 3 months for knowledge, attitude and practice).

X₂ - Presentation of Video Assisted Teaching Module regarding contraceptive methods and Emergency Contraception to the intervention group.

O₃ - Post-test II Knowledge, attitude and practice of couples’ regarding contraceptive methods and Emergency Contraception of control and intervention group. (In 6 months for KAP)

E (Effectiveness) = O₃ - O₁
Fig- 3.1 FLOW DIAGRAM OF RESEARCH DESIGN

RESEARCH APPROACH
Evaluatory approach

RESEARCH DESIGN
Randomized control trial

STUDY SETTING
Villages of Pondicherry

TARGET POPULATION
Eligible Couples present in the villages of Pondicherry

ACCESSIBLE POPULATION
Couples’ fulfilling inclusion criteria and willing to participate in the study

SAMPLING TECHNIQUE
Cluster randomization

SAMPLE SIZE- 1000 (500 in control group & 500 in intervention group)

Control Group

Intervention Group

PRE TEST

No VATM

VATM

POST TEST - I

Knowledge (in 1 month), attitude (in 2 months), KAP (in 3 months)

No VATM

VATM

POST TEST - II

Knowledge, Attitude & Practice in 6 months

ANALYSIS AND INTERPRETATION

DISCUSSION, SUMMARY, CONCLUSION, IMPLICATIONS AND RECOMMENDATIONS
3.2 Variables

Independent variable

In this study, independent variable is referred to Video Assisted Teaching Module (VATM).

Dependent variables

The dependent variables are referred to knowledge, attitude and practice of the couples on contraceptive methods including Emergency contraception.

Extraneous variables

The extraneous variables under the study are age, religion, education, income, occupation, type of family, no.of children, decision maker and source of information.

3.3 Setting of the study

Setting is the physical location and the condition in which data collection takes place in a study (Polit, 1995). The study was conducted in the community areas by covering with four villages namely Karrikalampakkam, Embalam, Korkadu and Uriviyaru of Pondicherry, 20 kms away from the town. The total population in these villages is around 24500. (Area Map indicates the villages for study).
Area Map of the Study Villages

- Sakaranpettai
- Pudukkupam
- Sadakulam pet
- Manakuppan
- Embalam
- Kambalikaranuppam
- Aranganur
- CHC
- Korkadu
- Melthirukanji
- Perungalur
- Thirukanji
- M.S
- P.S
- Uruwayaru
- Dhanathumedu
- Keezragarakam
- To Abhishekanakkam
- To Madukurai
- Karikalampakkam
- Nathamedu
- Nirmayapet
- Over Head Tank
- School
- Study Area
- Control Group
- Intervention Group
3.4 Population

“Population” for the present study deals with the couples whose wives were in the age group of 18-42 years living in the villages.

3.5 Sample and sample size

Sample is a subset of population, selected for this study were the couples whose wives in the age group of 18-42 years in the selected villages available within the period of study and fulfill the inclusion criteria.

Sample size

The sample size comprised of 1000 couples selected randomly, five hundred in each control and intervention groups. Sample size was determined by using similar study literature sources and the calculation is based on effect size and power analysis. The formula used to calculate the effect size was: \( \gamma = \mu_1 - \mu_2 / \sigma \) (difference between the means divided by the pooled SD)

The estimated sample size was approximately 415 in each group according to the effect size 0.25 and power of 0.95. The researcher increased and kept the sample as 500 in each group, keeping in mind about the drop outs and to cover almost all the couples who come under the inclusion criteria in the villages selected for the study. At the end of the study, the number of drop outs samples was 12 from the control group and 11 from the intervention group. The reasons, either they were not interested to attend the follow-up visits or they were conceived. As a result, these samples were not included in the study. So there were 488 samples in control and 489 samples in intervention group retained. Total number of drop outs of samples was 23 and the actual sample size was 977 for the present study.
3.6 Criteria for selection of Samples

Inclusion criteria

Married couples who

- were in the age group of 18-42 years.
- were with or without a child.
- were able to understand Tamil
- were willing to participate
- had no other complications like Cervix Cancer, STD, HIV and repeated abortions
- were present during the period of data collection

Exclusion Criteria

It deals with-

- The pregnant women
- The females who had undergone Hysterectomy
- Couples who had undergone permanent method of family planning

3.7 Sampling Technique

Cluster randomization sampling technique was used to select the samples for the study. Four villages of Pondicherry were selected randomly, for the study. Of which two villages were selected for Control Group and two villages were selected for Intervention Group by using simple random sampling. The villages were Karikalampakam, Embalam, Korkadu and Uriviyaru. Villages Karrikalampakkam and Korkadu were selected as Control Group whereas villages Embalam and Uriviyaru were selected as Intervention Group. Each village was considered as a cluster. From each cluster, the number of eligible couples was identified. The eligible couples were
about 1199, 763,607 and 1019 from the above villages respectively; however the eligible couples who fulfilled the inclusion criteria were 306,248, 211 and 291 respectively. The total eligible couples who met the criteria in the Control Group villages were 517 and couples in the Intervention Group villages were 539. 500 couples from Control Group villages and 500 couples from Intervention group villages were selected by simple random sampling for the study. However 488 couples for the Control Group and 489 couples for the Intervention Group were considered as samples for the study; as twelve from Control Group and eleven couples from Intervention Group were dropped out.

**Fig 3.2. Schematic Representation of Sampling Technique**

3.8 Development of the Tool

The tools developed for the study are

1. Structured-interview schedule for knowledge assessment,
   - Likert’s five-point rating scale for attitude,
   - Check list to assess the practice and

2. The Video Assisted Teaching Module on contraceptive methods.
Development, preparation and testing of the Tool

Structured-interview schedule was prepared to assess knowledge, Likert’s five-points rating scale to assess attitude and checklist for practices of couples’ regarding contraceptive methods including Emergency Contraception. The steps used for preparation of the tool are-

- Review of literature
- Preparation of the blue print
- Experts’ opinion and certification from the specialization field for content, construct and criterion validity.
- Consultation with the statistician for preparing the tool and plan for analysis.

Review of literature

Study related books, journals, reports from the Government, articles, published and unpublished research studies were used to develop the tool.

Preparation of the blue print

The blue print of items pertaining to knowledge, attitude and practice was prepared as per the objectives and conceptual framework. The blue print includes the meaning of contraception, different types of methods available, uses, and advantages of all the methods.

Opinion and certification from the Experts’ in specialization field

The blue print items were given to the experts in various fields such as Obstetrics & Gynaecology Nursing, Gynaecologist, Deputy Director of Family Welfare, Director of NRHM, Community Medicine specialist, Community Health Nursing, Statistician, and English. Their opinions and suggestions were taken into
consideration to modify the blue print. The research consultant and the Guide were consulted while finalizing the tool (*Annexures IX & X*).

3.9 Description of structured interview schedule (Annexures I & II)

The structured interview schedule consists of two parts.

**Part A**: It consists of demographic characteristics of eligible couples’ i.e. age, education, religion, income, occupation, type of family, number of children, decision maker and source of information.

**Part B**: It consists of 49 knowledge items on different contraceptive methods. It has sub sections such as:

- Couples’ knowledge on Family Planning
- Temporary methods like Condom, Oral Pills, Cu-T, Injectables and Emergency Contraception
- Permanent methods

**Scoring Procedure**

There were 49 items pertaining to the knowledge of contraceptive methods. Each item had four options with only one appropriate answer. The maximum score for correct response to each item was “one” and wrong response to each item was “zero”.

The level was categorized as:

<table>
<thead>
<tr>
<th>Level of knowledge</th>
<th>Actual Score</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate</td>
<td>0-24</td>
<td>50% or Less</td>
</tr>
<tr>
<td>Adequate</td>
<td>25-49</td>
<td>Above 50%</td>
</tr>
</tbody>
</table>
Part C

*Likert’s Scale:* It consisted of 33 statements on attitude aspects and five-point likert’s scale. There were 15 positive statements and 18 negative statements with a total score of 165.

**Scoring procedure for attitude statements**

The statements had 5 scores like 1- strongly disagree, 2- disagree, 3- neutral, 4- agree and 5- strongly agree. Maximum score for the positive attitude is 5 and the negative statement scored reversely. Thus the total score was 165. All these five scores were divided into 3 levels as Positive, Neutral and Negative.

<table>
<thead>
<tr>
<th>Levels of Attitude</th>
<th>Score</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>0-66</td>
<td>below 45%</td>
</tr>
<tr>
<td>Neutral</td>
<td>67-100</td>
<td>45-75%</td>
</tr>
<tr>
<td>Positive</td>
<td>101-165</td>
<td>above 75%</td>
</tr>
</tbody>
</table>

Part D

*Check List:* It consisted of six questions related to practice aspects of contraceptive methods. It was interpreted in terms of frequency and percentage according to the response of the respondents.

**Scoring of the practice aspect**

Practice aspect questions were analyzed by the use of frequency and percentage i.e if the couple adopted to any method given score “one” and if not then given “zero”.

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Video Assisted Teaching Module on contraceptive methods including Emergency Contraception

Video Assisted Teaching Module content was prepared on the basis of the following steps-

- Literature referred regarding the contraceptive methods including emergency contraception
- Organized the contents of video assisted teaching module
- Developed and established content validity of video assisted teaching module
- Preparation of the final draft of video assisted teaching module
- Edited video assisted teaching module
- Planned the schedule of procedure

Literature referred regarding contraceptive methods including emergency contraception

The literature (books, journals, reports, articles) regarding contraceptive methods including Emergency Contraception was referred to prepare the contents of Video Assisted Teaching Module.

Organization of contents of Video Assisted Teaching Module on contraceptive methods including Emergency Contraception (Annexures III, IV, XIV)

The contents are organized as follows:

a. Introduction.
b. Definition.
c. Purposes.
d. Types of methods.
e. Temporary methods (Condom, Oral Pills, Cu-T) and its uses.
f. Injectables and Emergency Contraception.
g. Permanent methods
h. Conclusion
3.10 Validity and Reliability of the Tool and Module

Validity

Validity refers to whether an instrument accurately measures what it is supposed to measure. The content validity of the tool was established in consultation with 10 expert’s i.e. Deputy Director of Family welfare (one), Director of NRHM (one), Specialist from social and preventive medicine (one), Specialist from community health nursing (two), Specialist from Obstetrics and Gynaecology nursing (two), obstetrician (two) and statistician (one) (Annexure XI). As per the suggestions of the experts the Researcher had made necessary modifications in the tool.

Translation of the tools

All the tools and the video assisted teaching module were translated into Tamil (local language) and certified by the expert who knows both languages and then it was retranslated into English to determine the correctness of the Tamil translated tool.

The criterion related validity is most often used in applied form of Research. In this study, Researcher has done a predictive validity on a contraceptive practice outcome based on the reviewed literatures. The reviewed literatures supported the criteria’s presented in the tool.

The construct validity, was obtained from the experts. The significance of the construct validity is its linkage between the theory and theoretical conceptualization. The construct validity was done using a method called multitrait-multimethod approach to strengthen the tool.

The VATM CD was displayed to the experts for the content validity and the recommendations were considered.
Reliability of the tool

During the pilot study, the reliability of the tool was established by using split half method for assessment of the level of knowledge. The structured interview schedule, which has 49 items in it, was divided into odd and even items, to check its internal consistency. The co-relation co-efficient was calculated using the Spearman-Brown Prophecy formula as follows:

\[ r^1 = \frac{2r}{1+r} \]

The calculated value of \( r = 0.92 \). There by the tool was considered as reliable with internal consistency. The other tools were attitude statements and check list to assess attitude and practice. Its reliability was checked again through split half method, with Spearman-Brown Prophecy formula. The obtained ‘r’ value was \( r = 0.87 \) for attitude and \( r = 0.78 \) for practice. The VATM was tested among 100 couples (those couples not included in the study) for reliability by test-retest method. \( r = 0.93 \). The tool was considered reliable.

Preparation of the final draft

Final draft of the structured interview schedule, attitude scales, check list and Video Assisted Teaching Module were prepared after testing the reliability and validity.

3.11 Pilot study

Pilot study was conducted from 100 samples (50 in control group and 50 in intervention group) during the period of 15th Dec 2007 to 15th Jan 2008 and analyzed for feasibility of the main study. The pilot study was conducted in Kalapet and Pillachavady villages of Pondicherry, which were not included as the main study area.
First, the pre-test was conducted among all the couples from 15.12.07 to 24.12.07 by an investigator. 10 couples were interviewed daily. It took 20-25 minutes approximately to interview one couple. After pre-test video assisted teaching module was shown only to the intervention group couples. VATM was arranged in a common place of the village and it was organized according to the convenient timing of the couples’. The schedule was planned to show the VATM on 27.12.07 from 2 pm to 5 pm in 5 sessions. Couples were divided into groups for video teaching. In each group 10 couples participated and doubts were cleared during teaching. Each session took on an average of 20 minutes.

After a week interval post test was conducted from 2.1.08 to 11.1.08 among all the couples and 10 couples were assessed in a day.

The findings of the pilot study showed that there was inadequate knowledge of the couples’ in both the control and intervention groups in pre-test, whereas there was significant improvement in the post-test knowledge score of intervention group in comparison to control group. The level of attitude and practice in the intervention group also improved in the post test as compared to control group. The above result helped the researcher to find out feasibility of the study and proceed for the main study. Questions with more than one answer made confusion to the couples, which were identified by the researcher. And they were modified after the pilot study according to the respondents’ views. These samples were not included in the main study. Schedule for data collection for pilot study is attached (Annexure XII).
3.12 Data collection procedure

Selection of Research assistant

The researcher had selected four research assistants with M.Sc. Nursing qualification for data collection. A Research assistant was selected for the each village of Karikallampakkam, Embalam, Korkadu and Uriviyaru respectively. Before the data collection, the research assistants were explained the purpose of the study and data collection methods. The research assistants were interested and willing to assist the researcher for the data collection.

Training to the research assistant

All the research assistants were trained by the researcher for 5 days (from 1st May to 5th May 2009). The method of interviewing the couple was demonstrated to them by the researcher. Timing for data collection and the inclusion criteria of the samples were explained.

Reliability of the research assistant

Both the researcher and the research assistants collected the data simultaneously during the training period for 5 days (1st May to 5th May ‘09) from 25 samples in the other area (not included in the study area) to test the reliability of the data collection by the research assistants. The inter-rator reliability was calculated to find out the correlation between the collected data of the researcher and the research assistants. The ‘r’ values were 0.80, 0.89, 0.9, and 0.87. Thus the reliability of the research assistants was established.
Methods of Data collection

Permission from the concerned authority

- Prior to data collection, written permission was obtained from the Govt of Pondicherry (*Annexure V*).
- Ethical clearance was obtained from the Ethical Committee (*Annexure VI*).
- Consent of the couples’ was taken prior to data collection and all couples were informed the date and time of interview (*Annexures VII & VIII*).

Schedule was planned before data collection and the data was collected in five phases

**Phase - I**

Pre-test was conducted in the four villages by the respective research assistants. Couples were interviewed for assessment of their knowledge, attitude and practice with the help of the tool prior to intervention. 10-13 couples were interviewed each day. Average time spent for each interview was 30 minutes. The pre-test was conducted from 6th May to 31st May 2009. Schedule is attached. (*Annexure XII*)

**Phase - II**

According to the convenience of the couples’, the video sessions were arranged in each village for 2 days in 10 sessions on each day from 12 Noon to 5 PM by the investigator. The video show was organized for the intervention group, on 1st & 2nd June in Embalam and on 3rd and 4th June, 2009 in Uriviyaru. Each session took around 20 - 25 minutes. Couples were informed before the VATM and the video was shown to the group of couples’ in a common place of the same village. 10 - 15 couples were shown the video teaching module in each group. (Schedule of VATM is attached. (*Annexure XII*)
Phase-III

Post-test I was conducted after one month of VATM (Video Assisted Teaching Module) for assessment of knowledge from 5th July to 30th July, 2009 in the four villages; assessment of attitude was done after 2 months of VATM, i.e from 5th Aug to 25th Aug 2009. After 3 months of VATM, the post-test was conducted for knowledge, attitude and practice assessment, i.e from 5th September to 30th September 2009. Schedule for data collection is attached (Annexure - XII)

Phase IV

After 3 months, once again VATM was shown to the intervention group of couples’ in the similar manner for 4 days, i.e from 1st to 2nd Oct in Embalam and from 3rd to 4th Oct, 2009 in Uriviyar, in ten-ten sessions in each village.

Phase-V

Post-test II, was conducted after 3 months of VATM, i.e from 6th February to 15th March 2010. Assessment was done for knowledge, attitude and practice of the couples’ using the same tools which were used in the pre-test. The total data collection period was 11 months that is from May 2009 to March 2010.

3.13 Plan for data analysis

The collected data were analyzed in terms of objectives by using both descriptive and inferential statistics. The collected data was organized, tabulated and analyzed by using descriptive statistics such as Frequency, Percentage, Mean, and Standard Deviation.

The inferential statistics such as Chi-square test, Co-relation Coefficient, Regression analysis, ‘t’ test and ‘F’ test were used to find out the association between
demographic variables with knowledge, attitude and practice scores, Co-relation between knowledge, attitude and practice, difference in knowledge and attitude and practice between control and intervention group, difference between the means of three post-tests in knowledge and attitude of the intervention group respectively. The data was presented in the form of tables and figures in the chapter - IV.

3.14 Ethical Consideration

- Research problem and objectives were approved by the Ethical Committee *(Annexure VI)*
- Written permission from authorities was obtained *(Annexure V)*
- Informed oral consent was taken from the couples *(Annexures VII & VIII)*
- Introduction was given and procedure was explained regarding the purpose of the study
- Confidentiality and anonymity were assured
- Freedom was given to the couples to withdraw from the study at anytime.

SUMMARY

This chapter deals with the research approach, research design, variables, setting of the study, sample and sample size, sampling criteria, sampling technique, development of the tool, description of the tool, content validity, reliability, pilot study, data collection procedures, ethical considerations, schedule for data collection for pilot study and main study, plan for data analysis by coding, tabulation etc.