CHAPTER 3
RESEARCH METHODOLOGY

“Great design is not just solution; it is the elimination of the problem”

M obanli.

INTRODUCTION:

A research methodology defines what the activity of the research is, how to measure the progress and what constitutes success. Methodology of research indicates that, it is a universal design for establishing the procedure for the pragmatic study collected with the method of gathering valid and consistent data for study.\textsuperscript{97}

This chapter will drive us to understand the methods of research which were used in the study to assess the comparison of verbal, written and video based health education regarding cervical screening tests on knowledge, attitude and participation of women for cervical screening in hospitals of Pune.

It contains the research approach, research design, setting of the study, identification of target population, sample and sampling technique, sample size, inclusive and exclusive criteria (subjects), tool preparation and feasibility of the study, pilot study, validity, reliability, development of data collection and plan for data analysis.

3.1 RESEARCH APPROACH:

It is systematic, objective method of discovery with an empirical evidence. The approach of the study depends on many factors but primarily on the nature of phenomenon under the study.\textsuperscript{97}

The research technique executed, for the project was evaluative approach because the study aims at assessing the effectiveness of intervention program regarding cervical cancer on knowledge, attitude and participation in cervical screening tests.
Figure No 2: Schematic Representation of Research Methodology
3.2 RESEARCH DESIGN:

Polit and Beck (2015) state that, it is the process of designing entire research plan which will be executed in order to gain the answer to the research question or to check the research hypothesis. The plan is made systematically and scientifically in terms of addressing the objectives and research questions involving the specification for enhancing the integrity of the study.98

The design adopted for the present the study was One group pretest posttest Quasi Experimental Design
Figure No 3: Representation of Research Design- One group pretest and posttest

Quasi experimental design.
3.3 SETTING OF THE STUDY:

Polit and Beck (2011) state that setting is place and environmental contexts, where the researcher plans to obtain the data for study. In this the study Urban Health Centre was selected as the setting. This urban health center is a 1000 bedded hospital with all health care facilities for diagnosis, treatment facilities. The study was conducted in Gynec Out Patient Department (OPD).

3.4 VARIABLES:

Variables are characteristics, quality or attribute of a person or object that the experimenter controls or observes. In the present study, three variables are recognized to include in the study, they are, independent variable, dependent variable and demographic variable.

3.4.1 Independent variables: Independent variable is the (treatment or experiment) process, in which the researcher will manipulate this variable to cause an effect on dependent variable. In the present study, independent variables are verbal, written and video based educational interventions.

3.4.2 Dependent variable: Dependent variable is the change in response, behavior or outcome which occurs after manipulation of independent variable in research. Knowledge, attitude and participation in cervical screening are the dependent variables in the present study.

3.4.3 Demographic variable: These are the factors which are not the part of the study but may affect the measurement of the study variable. Age, educational qualification, occupation, family income per month, religion, marital status, age at marriage, age at onset of sex etc are the demographic variables in the present study.

3.5 POPULATION According to Polit and Beck (2011) “it is the involvement of whole population who will be having common characteristics to include in the study and entitled to generalize findings on same. The population of the present the study covers the women age group between 30-60 years.
3.5.1 **Target population** According to Polit and Beck (2011) “Target population it is the aggregate of cases about which the researcher would like to generate”. In the present the study women age group between 30-60 years is the target population.

3.5.2 **Accessible population**: Accessible population is the aggregate of samples that approve to entitle the criteria and are also available as participants for the study. In the present study women age group between 30-60 years attending Gynec OPD.

3.6 **SAMPLE AND SAMPLING TECHNIQUE**: 

3.6.1 **Sample**: According to Burns Nancy and Grove Susan K (2012) “Samples is a subsection of the population that is recruited for a study”. Sample is used in research when it is not feasible to study the whole population from which it is drawn.

In the present study, women age group between 30-60 years attending Gynec OPD recruited as sample.

3.6.2 **Sampling technique**: According to Polit and Hungler (2015) “Sampling refers to the procedure of electing population to represent the entire population”.

In this study, Multistage Sampling Technique was used. Pimpri Chinchwad Muncipal Corporation Hospitals were identified from PCMC office. They are YCM Hospital, Bosari Hospital, Talera Hospital, Yamuna hospital and Sanghvi Hospital.

By using Simple Radom Sampling techniques, two hospitals were selected by adopting lottery technique. By assuming purposive sampling technique, Gynec OPDs were taken from two Hospitals. Allocated the Systematic Random Sampling Technique, ie Kth sample was selected as per the average daily attendance at Gynec OPD. Average attendance of women per day was 150, total probable attendance at Gynec OPD per month was 3900, per two months was 7800 and this was divided by sample size 501. The Kth sample was 15. First 15th participant was given verbal education, second 15th participant was given written education and third 15th case was given video based education and so on. The Researcher selected those units of
population as a sample that appeared random until the desired number of sample size was met.

3.6.3 Sample size: “Sample size is the number of subjects, events, behaviors or situations that are tested in a study.”

Calculation of sample size: with help of prevalence rate the sample size was obtained by the formula;

\[ n = \frac{Z^2 \times P \times (1-P)}{\varepsilon^2} \]

Where

Confidence level = 95% Therefore \( Z = 1.96 \)

\( P = 74.6 \) (heard about cervical cancer)

\[ n = (1.96)^2 \times 74.6 \times 25.4 / (4)^2 \]

\[ = 454.76 \]

\[ = 455 \]

Considering 10% dropout = 10% of 455 = 45.5 = 46

Total sample size (n) = 455 + 46 = 501

3.6.4 Sampling criteria: sampling criteria is the list of the features essential for inclusion and exclusion in the target population.

In the present study, inclusion and exclusion criteria were arranged in following manner;

Inclusion Criteria: Sample includes women who were;

- age group between 30-60 years
- Seeking help for reproductive related health services at the Gynec OPD
- resident of Pune Chinchwad Municipal Corporation
- able to read and understand Marathi /English
**Exclusion criteria:** Sample includes women who are:

- having severe medical and gynaecological illness
- not cooperative and not willing to participate in the study
- already diagnosed with cervical cancer and are on treatment
Figure No 4: Schematic Representation of Sampling Process
3.7 TOOLS AND TECHNIQUES:

The most important and crucial aspect of any research is data collection, which provides necessary information to answer the questions raised in the study. Data collection relies on the tool used for the study.

The data collection tool was constructed by the investigator in the light of literature reviewed and her experience in the clinical field to ensure the adequacy, relevancy, and question organisation, validity of the content and measurable too. The present study is aimed to assess the comparison of verbal, written and video based health education on knowledge, attitude regarding cervical cancer and participation of women in Pap smear tests.

3.7.1 Selection of Tool: Section I consisted of information related to socio demographic variables. Section II consisted of structured knowledge questionnaire Section III consisted of an attitude scale regarding cervical cancer. Section IV of the tool is on reasons for non-participation in cervical screening (before health education). Section V of the tool is on reasons for non-participation in cervical screening (after health education). Section VI of the tool is on reasons for participation in cervical screening among three experimental groups after attending health education. Section VII of the tool is on views of women regarding verbal health education on prevention and early detection of cervical cancer.

3.7.2 Preparation of tool: The tool acts as a best scale or measuring instrument to assess and collect the data from the participants of the study. The instrument selected in research, as far as possible be the vehicle that would best obtain conclusions pertinent to the study and at the same time add to the body of knowledge in the descriptive form. The present the study is aimed to assess comparison of verbal, written and video based health education on cervical cancer on knowledge, attitude and participation of women for Pap smear tests.

The tool was developed by the investigator in perspective of women age group between 30 - 60 years attending at Gynec OPD.
Investigator adopted following steps in the development of the tool:

a) **Extensive review of literature:** The investigator has referred various books, national and international journals, reports, published research studies, articles in the newspaper to find the information about cervical cancer and its preventive measures. The investigator has visited the various libraries in Pune, Mumbai for a wide reviewing the literature about the cervical cancer.

b) **Consultation with experts:** The investigator has approached many organizations such as Federation of Obstetrics and Gynecology Society in India (FOGSI), Pune Obstetrics and Gynecological Society (POGS), Film and Television Institute of Technology in India (FTII) and experts from the field of obstetrics and gynecological nursing to gather the information strategies to reduce the prevalence of disease condition.

c) **Development of blue print of questionnaire:** Structured questionnaire was made to assess the knowledge on prevention and early detection of cervical cancer (Pretest and posttest). It contains 37 items and was under following headings: Introduction and definition 5.12%, risk factors of cervical cancer 25.64%, symptoms of carcinoma of the cervix 20.51 %, measures to reduce the risk of cervical cancer 23.07% and screening procedures and HPV vaccine 25.64%

- Likert type scale was to assess the attitude (Pretest and posttest). Which has 13 items
- Checklist was used to assess reasons for non-participation in cervical screening (Pretest). It contains 15 items and checklist was used to assess the reasons for non-participation in cervical screening (After Health Education). It contains 13 items.
- Reasons for participation in cervical screening among three experimental groups after attending Health Education. It contains 8 items and views of women regarding verbal, written and video based health education on prevention and early detection of cervical cancer was assessed by yes or no types of questions. It contains 4 questions (Annexure E Enclosed).
d) Construction of demographic proforma:

Demographic details related to primigravida women was constructed which included; age in years, educational qualification, occupation, family income per month, religion, marital status, age at marriage (years), duration of marriage (years), age at onset of sex (years), age at first child birth (years), lifetime sexual partners, number of pregnancies continued past 32 weeks, number of children etc.

e) Validity of the Tool:

Tool presentation was done in front of tool validation committee of Mahatma Gandhi Memorial Institute of Health Sciences (MGMIHS), with suggestions and guidance from various experts, tool validity was achieved.

Tool validity also was done by experts of FOGSI, Pune Obstetrics and Gynecological Society (POGS) and Gynec department of PCMC hospitals.

f) Conducting a pilot study:

Pilot study was conducted with an aim to examine the ability of the instrument to be administered to gather the data and find feasibility of the study, arithmetical calculations analysis and possibility of research study to implement in the main study. 17 subjects were included in each group (17 in verbal, 17 in written and 17 video groups). Gynec OPD was nominated using simple random sampling technique. The analysis was done and findings were found reliable, the main study was found to be feasible for conduction based on findings of pilot the study.

g) Reliability of the Tool:

To assess reliability of the tool Cronbach’s alpha was applied. Cronbach’s alpha is calculated as total score of each item for each observation is correlated and then compared to the variance for all individual item score. The value of Cronbach’s Alpha (α) as evaluated for the scored questions pertaining to aforesaid factors of this study is 0.98, which can be interpreted as ‘Excellent’ as per predefined value ranges and their interpretations.
3.7.3 Description of Tool: The tool consists of seven sections:

**Section I**: Demographic variables are age, educational, occupation, income, religion, marital status, age at marriage (years), duration of marriage (years), age at onset of sex (years), age at first child birth (years), lifetime sexual partners, number of pregnancies continued past 32 weeks, have you ever screened for cancer of the cervix, if yes how many times screened since you become sexually active, when was the last time you have screened, have you ever smoked, have you ever used temporary family planning methods, if yes what type of temporary family planning methods have you used, did any one of your family members ever had cervical cancer and where did you first learn about carcinoma of the cervix.

**Section II: Knowledge Questionnaire on prevention and early detection of cervical cancer**

Structured questionnaire was prepared to assess the knowledge. It includes 37 items and was divided under following headings; in regard to introduction and definition of the cervical cancer, there were two questions which had 4 options and one option will be the right answer.

From three to five questions were designed in regard to knowledge on risk factors of cervical cancer, symptoms of carcinoma of the cervix, measures to reduce the risk of cervical cancer, knowledge on screening procedures. All questions had multiple options, right answer could be more than one, the responses to each option were yes / no and don’t know.

Question number six to eight had four options and one could be the correct answer.

Question number nine was in regard to cervical screening, HPV vaccine and had the multiple options and answer should be the more than one.

**Scoring:**

1. Right answers score allotted is 1 mark

2. Wrong answers score allotted is 0 mark
Categorizing of scores: the summed scores is categorized as below;

- Excellent knowledge score >70%
- Moderate knowledge score between 50-70%
- Good knowledge score between 40-50%
- Poor knowledge score <40%

Section III: Attitude scale on prevention and early detection of cervical cancer: In this section Likert’s scale was used to assess the attitude of women. This scale had a set of 13 statements to assess the attitude. These 13 statements had five options namely; strongly Agree (SA), Agree (A), Neither Agree Nor Disagree (NAND), Disagree (D), Strongly Disagree (SD).

The option of ‘Strongly Disagree’ is the sought after option as it indicates a healthy attitude. Scoring is Strongly Agree:5, Agree: 4, Neither Agree nor Disagree :3, Disagree :2 and Strongly Disagree: 1. Score calculated maximum was 65 and minimum was 13.

Categorizing of scores: The summed scores are categorized as below;

Positive attitude score was: 27 - 65

Negative attitude score was: 13 - 26

Section IV: Reasons for non-participation in cervical screening (Before Health Education)

This scale included 15 items to find out the reasons why have they not participated in cervical screening. These 15 statements had two options namely; Yes or No.

Section V: Reasons for non-participation in cervical screening (After Health Education). This scale included 8 items to find out the reasons why have they not participated for cervical screening even after attending the intervention. These 8 statements had two options namely; Yes or No.
Section VI: Reasons for participation in cervical screening among three experimental groups after attending Health Education. This scale included 8 items to find out the reasons why have they not participated for cervical screening even after attending the health education. These 8 statements had two options namely; Yes or No.

Section VII: Views of women regarding educational interventions, this scale included 4 items to find out the views of women regarding educational interventions. These 4 statements had two options namely; Yes or No.

3.8 VALIDITY:

Validity refers to the finding results accurately reflect the perception being measures. In Practice validity can also refer to the accomplishment of the research in saving valid results. Content validity and face validity of tool for conduct of study was done by the experts of tool validation committee of Mahatma Gandhi Memorial Institute of Health Sciences. The content validity of three interventions (verbal, written and video) was done by experts of FOGSI, POGS and PCMC.

3.9 RELIABILITY:

To assess reliability of the tool Cronbach’s alpha was used. Cronbach’s alpha is calculated as total score of each item for each observation is correlated and then compared to the variance for all individual item score. The tool consisted of structure questionnaire on knowledge, attitude, reasons for participation and non-participation of women in cervical screening and views about interventions.

The reliability was calculated using value of Cronbach’s Alpha (α) method for knowledge and attitude questionnaire. It was found reliable that is \( r = 0.98 \) for knowledge and \( r=0.85 \) for attitude questionnaire. The knowledge and attitude questionnaire found to be reliable.

3.10 PILOT STUDY:

Pilot study was conducted from 2-11-2015 to 30.11.2015 and the aim of pilot study was to examine the consistency of questionnaire, which is proposed to apply during the time of data collection in the main study and also it intends to examine the
feasibility of the study. It gives direction to the researcher to decide the kind of tests to be used in the statistical analysis. Formal permission was obtained from the administrative department of the hospital, Matron and sister incharge of the OPD. Simple random sample technique was executed to gather the study samples. Informed consent was acquired from the participants. Subjects comprised in pilot study were marked exclusion in the main study. The analysis and communication was done, findings found reliable, the tool found to be feasible to conduct the main study.

It ha been guided the researcher to examine the feasibility of questionnaire, determine the time of implementing data collection. The present study was found to be feasible and directed in scheduling the pretest, intervention, posttest, reminders and follow-up.

3.11 DATA COLLECTION:

Collection of appropriate information is the most crucial aspect of any investigation, information collected provides necessary data to answer the questions raised in the study.

a) Permission from concerned authorities: Formal permission was obtained from respective hospital authorities to conduct the study. Written informed consent was acquired from subjects before administering tool and assured the confidentiality throughout the study.

b) Period of data collection: The data collection process was conducted between 01-06-2017 to 31-12-2017. Each subject was explained about the study and its purpose. The data collection was done strictly under the standard and laid down conditions. The criteria of the study were kept in mind while selecting the samples.

c) Methods of data collection: Data collection is an essential part of any research study. The sample was collected as per the laid down criteria and the data collection was done after completion of following formalities.
Approval of Ethical Committee of University (Annexure B) Permission from the concerned authority of selected Urban Health Centre (Annexure C) written informed consent from each subject (Annexure H)

**Technique for data collection:**

**Phase I:** Informed written consent, interview

**Phase II:** Pretest

**Phase III:** Intervention

**Phase IV:** Invitation for cervical screening on the day of intervention

**Phase V:** Cervical screening on the day of intervention who were ready to participate

**Phase IV:** Posttest (After 15 to 30 days)

**Phase V:** Consequent screening dates were given to women, those who had not participated in screening on the day of intervention

**Phase VI:** 1st Reminders for cervical screening by written letters (after 15 days of intervention)

**Phase VII:** 2nd Reminders for cervical screening by SMS (after 15 days of first reminder)

**Phase VIII:** 3rd Reminders for cervical screening by telephone call (after 15 days of 2nd reminder)

**Procedure for data collection:**

It is the most time consuming step of research process, which involves direct or indirect interaction with participants to gather information pertaining to the topic under the study. Formal administrative permission was obtained from the ethical committee of the institution for conducting the final study. Then investigator has officially visited the hospital authorities to obtain the formal permission and cooperation to execute the thesis. The procedure of project was described to the
Medical Director and assurance was given that no changes will be done in routine OPD functions by conduct of present study. The data collection process began from 01-06-2017 to 31-12-2017. Subjects who met inclusion criteria were determined. Multistage sampling technique was used to assign subjects in study groups. Written consent was taken from the participants, explained about the pretest, posttest questionnaire, time duration needed; scoring system was explained to the subjects. They were also given assurance regarding confidentiality of their scores and reports.

Investigator approached the subjects when they visited the Gynec OPD. Interview technique was implemented to collect the data and filling the questionnaires. Face to face education was done for verbal group, video based education for video group and distribution of information modules to the written group was executed. Invitation letters were given to all the participants for cervical screening programme on the day of intervention. Letter, SMS and telephonic call reminders were sent to the participants after 15 days of invitation consecutively. 15 days of gap was maintained in between each reminder.

3.12. PLAN FOR DATA ANALYSIS:

In the procedure of data collection raw data proposed to convert in to meaningful data or drawing of the meaningful results from raw data after the after applying systematic statistical analysis. Descriptive and inferential statistics were applied for the present study. The collected data was arranged in tables, figures, numbers and graphs. Various tests like Mean, Median, frequency distribution, Wilcoxon test Chi-square (McNemar), ANOVA and Tukey’s tests were applied.
3.13 SUMMARY:

This chapter on research methodology deals with the research design, research approach, setting of the study, description of population, sample and sampling technique, developing and testing of the tool, feasibility and pilot the study along with reliability and validity, method of data collection and plan for data analysis.