CHAPTER 3

Methodology

The methodology of research indicates general pattern for organizing, procedure of gathering valid and reliable data for an investigation. It represents the research design, variables, setting of the study, population, sample, sampling technique, sample size, development of tools, validity and reliability of tools, techniques of data collection and the plan for data analysis.

3.1 Research Design

A research design is the overall plan for acquiring new knowledge or confirming existing knowledge. The research design is the plan for a systematic approach, conducted in a way that ensures that the answers found will be as meaningful and accurate as possible[94].

Quasi experiments, like true experiments involve an intervention. However quasi experimental designs lack randomization, the signature of a true experiment. The signature of a quasi experimental then is an intervention in the absence of randomization. It functions to answers questions involving prediction and effects of manipulation. In one group pre-test and post test design, the group is observed before and after the independent variable is introduced[94].

This study uses the quantitative research approach. A quasi experimental study with one group pre-test post test research design was considered best suited to the study. This design was used since the study evaluates the effect of planned teaching

(Independent variable) on knowledge and self expressed practices of women (Dependent variable). The base measure was the knowledge a nd self expressed practices scores (0_1 x 0_2) and the experimental variable was planned teaching depicted as X. The research design can be presented in figure...

O_1 X O_2

This design was selected since it lacks randomization and control. The measurement of knowledge and self expressed practices were done immediately before and 28-30 days after the planned teaching. Schematic representation of the research design is illustrated as ***figure 2***

3.2 Variables under study

Based on the objectives of the study the variables of the study are:

Dependent - Knowledge and self expressed practices of perimenopausal women are in relation to management of selected physical components of menopause. The selected components are nine symptoms and two long term effects of menopause causing health hazards.

Independent - Planned Teaching on management of selected physical components of menopause affecting HRQoL. The selected components are nine symptoms and two long term effects of menopause causing health hazards.

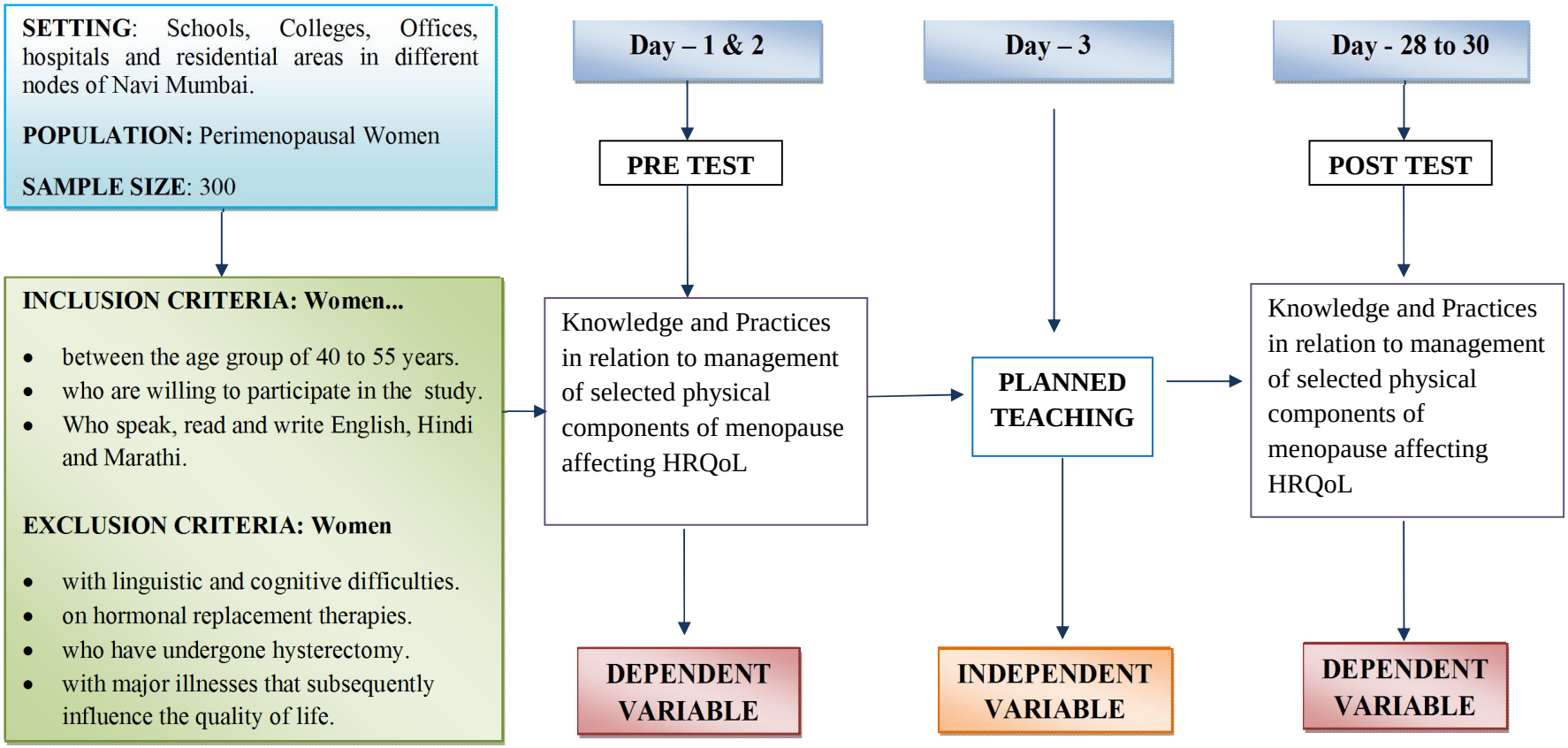

Figure 2: **Schematic representation of research design**

3.3 Setting of the Study:

The study was conducted in different residential areas, schools/colleges, offices, hospitals and some traditional local organizations like mahila mandal and other social clubs located in different nodes of Navi Mumbai. The different nodes are Vashi, Nerul, CBD, Koparkhairne, Kharghar and Panvel Navi Mumbai.

Navi Mumbai has a total population of 2,100,000 of which approximately 600,000 come from Nerul and about 400,000 from Vashi with the remainder from Belapur, Kharghar and Koparkhairne and surrounding areas. The women population residing in Navi Mumbai is figured as 3, 08,297 (three lacks eight thousand two hundred and ninety seven) according to the census records, 2001 of Navi Mumbai Municipal Corporation (NMMC), and City and Industrial Development Corporation (CIDCO) of Maharashtra limited.

Navi Mumbai, formerly known as 'New Bombay' is one of the largest planned cities in the world, with a total area of 344 km² and 163 km² under the jurisdiction of the Navi Mumbai Municipal Corporation (NMMC). The NMMC, for the purpose of administration has been divided into 14 nodes. These nodes are Airoli, Ghansoli, Kopar Khairane, Vashi, Sanpada, Nerul, CBD Belapur, Kharghar, Kalamboli, Kamothe, New Panvel, Ulwe, Pushpak and Dronagiri. Each of the nodes is divided into smaller groups called sectors. The newly developed nodes of Navi Mumbai on the south side like Kharghar, Kalamboli, and New Panvel. The health services in Navi Mumbai include hospitals and clinics from various systems of medicine like allopathic, homeopathic, Ayurvedic etc. To cater to the health needs of people residing in the peripheral areas of

Navi Mumbai, NMMC has its urban health posts located at different nodes of Navi Mumbai. (Appendix B)

3.4 Population, Sample, Sample Size, Sampling Criteria and Sampling Technique

3.4.1 Population

A population is the entire aggregation of cases in which a researcher is interested. In this study, the population includes perimenopausal women, who are residents of Navi Mumbai.

3.4.2 Sample:

A sample is a subset of population elements. An element is the most basic unit about which the information is collected.

The samples included in this study were women in the age group of 40 and 55 years who are residing in Navi Mumbai.

3.4.3 Sample Size:

The sample size was determined to have larger group so that any unusual or systemic factors that could bias the study will be eliminated by the number of subjects. Based on the mean overall score of the pilot study and its Standard Deviation with a 95% Confidence Interval (CI) using Primer statistical calculator the sample size was estimated to 300. This amounts to taking the assessment of 300 samples during pre-test and again during post test after an interval of four weeks. A total of 307 participants were selected as per the inclusion and exclusion criteria. Since seven participants could not appear for post test, the sample size remains to 300.

3.4.4 Sampling Criteria

Inclusion Criteria:

Women who met the following criteria were included in the study.

- Women in the age group of 40 -55 years.
- Women who are willing to participate in the study.
- Women, who speak, read and write English, Hindi or Marathi.
- Women who are residents of Navi Mumbai.

Exclusion Criteria:

- Women with linguistic and cognitive difficulties.
- Women on hormonal replacement therapies.
- Those who have undergone hysterectomy.
- Women with major illnesses that subsequently influence the quality of life.

3.4.5 Sampling Technique

Nonprobability convenient sampling technique was used in the study. From the 14 nodes of Navi Mumbai, three nodes were used in order to develop the instrument and conduct pilot study. Hence these three nodes were excluded from the main study. The investigator enumerated the baseline characteristics of the remaining 11 nodes using the data from the local governing bodies like NMMC and CIDCO. The nodes were selected based on the baseline characteristics like total population, women population, availability of offices and educational institutes and the transport facility. The investigator approached women working in the schools/colleges, government/private offices and hospitals. The women from local organizations such as mahila

mandals/social clubs and housewives from the residential areas of these nodes were also contacted for this purpose.

A total of 307 women, between the age group of 40 and 55 years, belonging t o lower and middle socioeconomic class were selected from Vashi, Nerul, CBD, Koparkhairne Kharghar and Panvel Navi Mumbai. The samples were selected through snow ball technique in which, first contacts were made with few women of the above mentioned age group and then they were asked to identify other women participants of the same age group who are meeting the inclusion and exclusion criteria of the study. The pre test, intervention and post test in one area was planned in such a way that there is no contamination of the samples.

3.5 Instrument (Appendix- I)

3.5.1 *Development of instrument:*

The instrument used to assess the knowledge and self expressed practices of women during perimenopause was a self administered structured questionnaire and an information booklet

The instruments were developed by the investigator from extensive literature review, input from the experts as well as from women during perimenopausal age. The process of questionnaire development consisted item selection, item reduction and item presentation. Hence a large pool of possible items was generated through extensive literature review and carefully crafted to reflect the latent variable they were designed to measure. Various generic measures of quality of life questionnaire s like Women's Health Questionnaire, Menopause Specific Quality of Life and WHO quality of life

questionnaire were reviewed to select one evaluating quality of life during perimenopause. Menopause Rating Scale was used to assess menopause symptoms, affecting HRQoL.

The items were inspected carefully for clarity, length, good wordings and readability of the scale. A panel of eighteen experts consisting of three gynaecologists eight nurse educators, two physiotherapists, two statisticians and two women between the age 42 and 45 years were involved for establishing the content validity of instrument. The suggestions from experts were incorporated and necessary modifications were made in the instrument.

The instrument was tested on 30 women between age s of 40-55 years to identify relevance and addition of any new items in the questionnaire and information booklet. Minor changes were made in the two sub items after the pilot study.

3.5.2 *Description of the instrument*

The structured questionnaire consisted of five parts - Part I, Part II, Part III, Part IV and Part V (Appendix- D)

Part I

Section A: Demographic Data - 06 items

Section B: Personal Data - 18 items

Part II This part of the tool consists of self reporting Menopause Rating Scale, used to assess the existing symptoms of menopause affecting of physical HRQoL in relation to menopause. Menopause Rating Scale - 08 items

The Menopause Rating Scale (MRS)[95] was developed in the early 1990s by Juergen Dinger and Lothar A.J. Heinemann, in response to the lack of standardized, validated scales for measuring the severity of symptoms associated with Menopause, and the impact of these symptoms on health -related quality of life (HRQoL). The objective was to develop a scale that would be easy to complete by the women themselves. Designed and standardized as a self administered scale (patient reported outcome). The MRS: assesses symptoms/complaints of aging women under different conditions and in different countries, evaluates the severity of symptoms over time and assesses changes during treatment. The scale is easy to complete a nd can be evaluated quickly. It is available in 22 language versions that are cross -cultural equivalent: The MRS measures 11 items (complaints or symptoms), each on a scale from 0 (no complaints) to 4 points (very severe symptoms). The 11 items are grouped into three independent dimensions: 1) psychological domain 2) Somato -vegetative domain 3) Urogenital domain.

In this study Somatic and Urogenital domain were part of this tool.

Part III consisted of 21 items for assessment knowledge in relation to selected physical components of menopause.

Item 01- 04 - Female Reproductive System

Item 05 - 06 - Menopause

Item 07 - 09 - Hot Flashes and Night Sweats

Item 10 - Heart Discomfort

Item 11 -12 - Sleep Disturbances

Item 13 - Joint Pain

Item 14 - Urinary Problem

Item 15 - Vaginal Problem

Item 16 - Sexual Problem

Item 17- 18 - Gain in weight

Item 19 - 21 - Health Hazards

Part IV consisted of 08 items for assessment of self expressed practices in relation to management of menopause.

Item 01 - Hot Flashes and Night sweats

Item 02 - Heart Discomfort

Item 03 - Sleep Disturbances

Item 04 - Joint Pain

Item 05 - Urinary Problem

Item 06 - Vaginal Problem

Item 07 - Sexual Problem

Item 08 - Gain in weight

Part V consisted of 3 items Likert scale to find out the views of women regarding the information booklet. The Likert scale was scaled as strongly agree, agree, neither agree nor disagree, disagree and strongly disagree. A blank space was also provided for suggestions, if any.

3.5.3 Scoring and interpretation

The information related to demographic and personal data of women were not scored. The items concerning assessment of existing status of physical HRQoL in relation to menopause are scored by using 5 point scale to measure the severity of symptoms. The scale scores zero- being no symptom at all, mild - 1, moderate - 2, severe- 3 and very severe – 4 score. The items in relation to knowledge and self expressed practice on management of selected physical components of menopause affecting HRQoL (Part III & Part IV) were scored, based on the number of correct answers. A score of one was given to every right answer and score zero to every wrong answer, “do not know” answer and to all unanswered items. Many questions had more than one correct answer, ranged from 1 – 6 scores.

The total Knowledge score was – 120 and total practice score was – 50

The resulting scores for knowledge and practices were interpreted as follows:

Excellent	-	75% - 100%
Very Good	-	60 % - 74%
Good	-	46% - 59%
Average	-	26% - 45%
Poor	-	10% - 25%
Very Poor	-	less than 10%

The responses in relation to views of women regarding information booklet was scored as, strongly disagree 1, disagree 2, neither agree nor disagree 3, agree 4, strongly agree 5.The total scores for views in relation to content was 20, presentation 20 and language 15. The resulting scores content and presentation were interpreted as

Strongly agree	-	above 75%
Agree	-	60% - 74%
Neither agree nor disagree	-	45% - 59%
Disagree	-	30% - 44%
Strongly Disagree	-	less than 30%

3.5.4 **Validity and Reliability** (Appendix- C)

Validity reflects how accurately the instrument yields information about the true or real variables studied. A measure is valid if it measures correctly and accurately wh at it is intended to measure. The content validity of the instruments was determined by getting the opinion from a panel of eighteen experts consisting of three gynaecologists, eight nurse educators, two physiotherapists, two statisticians and two women between 42 and 45 years age. The suggestions from experts were incorporated and necessary modifications in the tool were made.

The reliability of the tool was established by using test , retest and analyzed using co efficiency alpha (Cronbac h's alpha) as a measure agreement. Analysis r evealed an overall score of 0.96 indicating a strong internal consistency.

3.6 Instructional manual (Appendix- J)

The instructional manual was developed by extensive review of literature, research articles, text books and manuals The content validity of the instruments was determined by getting the opinion from a panel of eighteen experts consisting of three gynaecologists, eight nurse educators, two physiotherapists, two statisticians and two women between 42 and 45 years age. The suggestions from the experts were incorporated and necessary modifications were made. After ascertaining content validity the instructional manual was translated from English to Marathi and Hindi by two different experts.

3.7 Pretesting

The tool and instructional manual were pretested on 10 women for feasibility and practicability. A few modifications were made and validated again.

3.8 Ethical Consideration

This study has been approved by the Institutional Ethical Review Co mmittee of Bharati Vidyapeeth University, Pune India. (Appendix -E)

3.9 Pilot Study

The pilot study was conducted from August 2009 to October 2009. A group of 30 women between the ages of 40 and 55 years were identified by using nonprobability convenient, snow ball sampling technique in which a few women participants were contacted first and requested to suggest more participants. The women were then approached by the investigator and th ose who met the inclusion exclusion criteria, were enrolled in the study. The participants were informed of the researcher's name, purpose and the procedure of study in advance. Consent forms were then obtained on the

consent form approved by ethical committee of BVPDU Pune, from those who were willing to participate in the study. Part I of the questionnaire which includes demographic and personal data was given to the participants to fill and next date and venue for the meeting was informed.

On the next scheduled meet, first, the participants were made to sit comfortably and then once again they were introduced to the investigator, explained the purpose and procedure of the study. The questionnaires were distributed and necessary instructions, pertaining to filling up of the structured questionnaire were given. After 30 to 45 minutes the questionnaire was collected and planned teaching program was administered in two sessions of 45 minutes each. The participants were given a tea break in between the first and second session. The post test was conducted after four weeks (28-30 days) using the same questionnaire.

3.10 Results of Pilot Study

Data analysis revealed that the study is feasible. The data was analyzed and modifications were made in the instruments after content validity and post pilot study.

3.11 Data collection (Appendix- G)

The data collection was done from October 2009 to April 2010. The investigator established rapport with the participants by meeting them personally either at their home setting or work place. Permission from heads of the institutions was obtained for the venue and the participants, for those who were employed. The purpose of the study was explained to all the participants and a written consent was obtained. The data was

collected mostly during afternoon and evening hours between 3PM and 7 PM on working days and between 11AM and 7 PM on Saturdays and Sundays depending upon availability of the participants. Trained research assistants were also involved in distributing questionnaires and clarifying the doubts of the women participants. The self administered questionnaires were distributed in English/Hindi/Marathi depending upon the demand by the study participants. The venue for planned teaching programme was mostly in the school building, office meeting rooms, coaching centres, community halls and home settings.

Two graduate nurses, working with the investigator were trained regarding the procedure of filling the questionnaire and gathering some physical measurements as required in Part I- section B of the questionnaire. They are referred as trained research assistants, in this study.

3.12 The data collection process was continued as follows

Phase I

The investigator collected information regarding women population and availability of samples from the local governing bodies of Navi Mumbai like the Navi Mumbai Municipal Corporation (NMMC) and City and industrial Development Corporation (CIDCO) and by local survey of the community. Letters from both the departments were received for authentic statistical information regarding women population in Navi Mumbai. (Appendix- F)

A period of three months had been spent in collecting community information and enumerating baseline characteristics and identifying the areas from w here data was to be collected.

Phase II

Six nodes of Navi Mumbai as per the baseline characteristics of the area were selected. Some women leaders were identified from the residential a reas, schools, offices and local organizations like mahila mandal/ social clubs of these nodes. These women leaders were requested to refer more participants from the selected community. Many participants were networked by these initially identified women and a list of those with their contact numbers was prepared. Hence a snow ball sampling technique was used.

Phase III

The women were then approached by the investigator and those who met the inclusion exclusion criteria, were enrolled in the study. The participants were informed of the researcher's name, purpose and the procedure of study and assured regarding the confidentiality of data, before initiating the interview. A written consent (Appendix-H) was obtained and Part I of the self administered ques tionnaire was distributed with necessary instructions in English/Marathi/Hindi as per the choice of the participants. Height, weight, waist circumference and hip circumference measurements were obtained by the trained research assistants as required under section B of part I for gathering personal data of the women. The date and venue for next meet was decided.

Phase IV

After ascertaining the comfort of the participants the pre test questionnaire in English/ Marathi/ Hindi (as per the choice of participant) were administered and necessary instructions were given by the investigator. The questionnaires were collected after 30 minutes to 45 minutes.

A verbal permission from the participants was obtained before the starting the session for taking some photographs during the session only for the purpose of this study. (Appendix -J)

Phase V

Intervention: The intervention in this study was the Planned Teaching Program in relation to management of selected physical components of menopause affecting HRQoL. The content of this teaching program was developed by the investigator from review of literature as well as from the input from fourteen experts. The content included in the teaching program was, brief description of structure and functions of female reproductive system, menstruation menopause, and management selected physical symptoms like hot flashes, night sweats, heart discomfort, sleep disturbances, joint pain, urinary problem, vaginal problem, sexual problem, weight gain, health hazards and health screening during menopause.

The teaching was conducted either in a class room, a community centre or a home setting where there is sufficient space to accommodate at least 15 participants and availability of electricity plug points. The investigator used LCD projector, laptop with pictorial power point slides as well as natural seeds like flax seeds, sesame seeds as a teaching aid.

The teaching program was conducted in two sessions on the same day. The first session covered description of structure and functions of female reproductive system, menstruation menopause, selected physical symptoms like hot flashes, night sweats, heart discomfort, sleep disturbances, and joint pain and their management. The second section included the urinary problem, vaginal problem, sexual problem, weight gain and health hazards of menopause like cardiovascular diseases and osteoporosis. A tea break was given between the two sessions. The duration of teaching was 1hour 30 minutes. An information booklet was distributed at the end of the session.

The total time spent including pre test was 2 hours which was extended up to 3 hours since the participants intended to clarify their doubts after the teaching. Teaching method used was lecture and discussion. Comfort, confidentiality and privacy of the participants were maintained.

Phase VI

Post test was done by the investigator along with the trained research assistants after four weeks (28 – 30 days).

3.12. Data analysis

The data analysis was done using Statistical Package for Social Sciences (SPSS) computer program – 17 version. The analysis of data is presented in following chapter.

Summary

This chapter deals with the research methodology adopted for the study and includes description of the research approach, research desi gn, setting, sample, sampling technique, data collection instrument and its development, instruction manual, validity, reliability, plan of data collection.