Chapter 3

Research Methodology

This chapter presents the research approach, research design, variables under study, diagrammatic representation of the design, research hypotheses, proposed setting of the study, population, sample and sampling techniques.

It also describes the data collection tool, its selection and development and scoring, content validity and reliability.

The chapter also records details about the pre-testing, pilot study, procedure of actual data collection and plan for data analysis.

3.1 Research approach and design

The study uses the quantitative research approach. A quasi-experimental approach with same group pre test post test design was considered best suited to the study as it aims to find out the effect of planned teaching on knowledge, HRQoL and practices related to selected components of health related quality of life in hemodialysis patients. Schematic representation of the research design is shown as Figure 2.
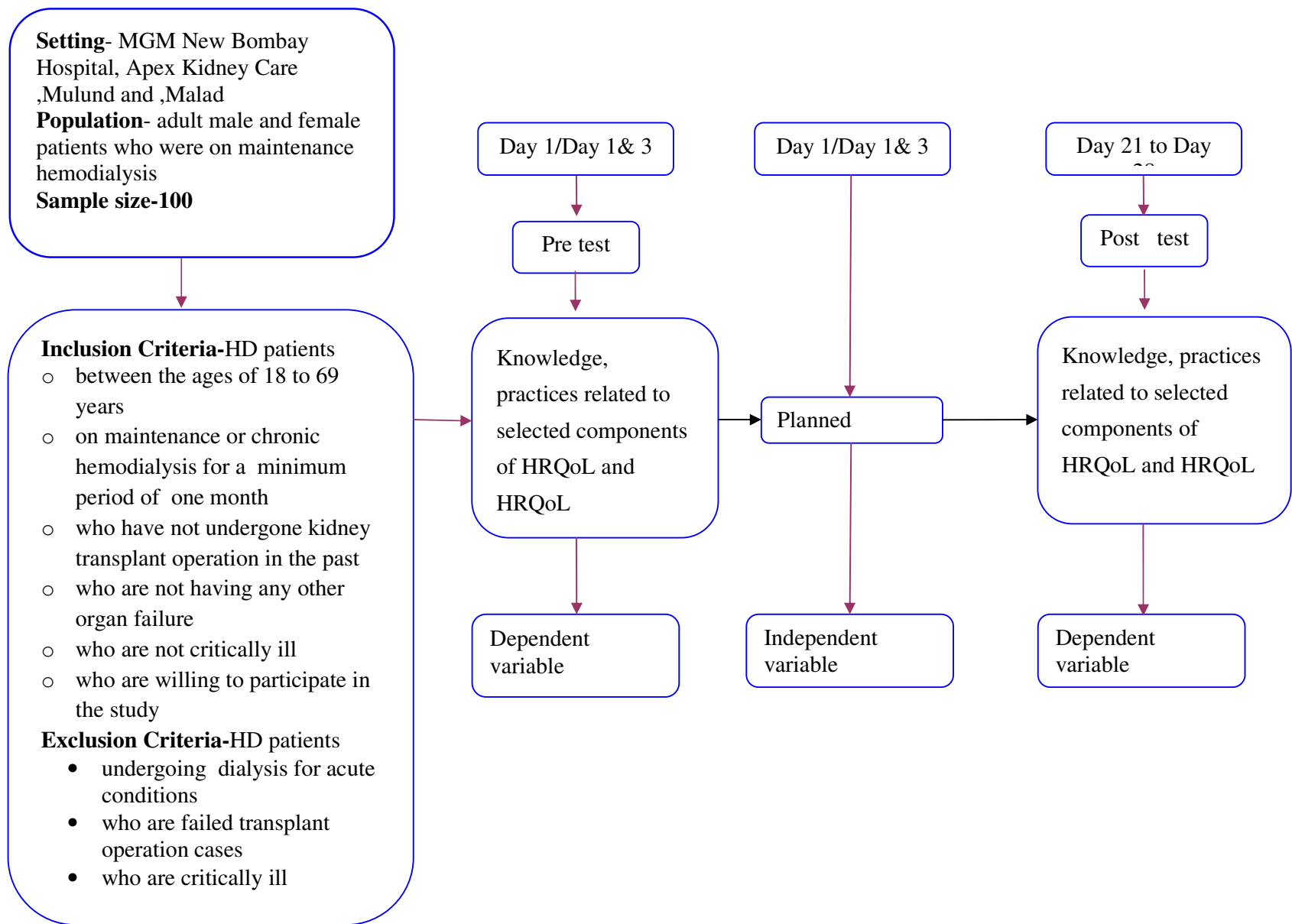
Setting- MGM New Bombay Hospital, Apex Kidney Care ,Mulund and ,Malad
Population- adult male and female patients who were on maintenance hemodialysis
Sample size-100

| Day 1/Day 1& 3 | Day 1/Day 1& 3 | Day 21 to Day |

Pre test

Post   test

Inclusion Criteria-HD patients
o   between the ages of 18 to 69 years
o   on maintenance or chronic hemodialysis for a minimum period of one month
o   who have not undergone kidney transplant operation in the past
o   who are not having any other organ failure
o   who are not critically ill
o   who are willing to participate in the study
Exclusion Criteria-HD patients
•   undergoing dialysis for acute conditions
•   who are failed transplant operation cases
•   who are critically ill

Knowledge, practices related to selected components of HRQoL and HRQoL

Planned

Knowledge, practices related to selected components of HRQoL and HRQoL

Dependent variable

Independent variable

Dependent variable

Figure 2 Schematic representation of the research   design

3.2   Variables under study

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

Dependent variables are knowledge, HRQoL and practices of hemodialysis patients related to selected components of HRQoL. The selected components of HRQoL are the 12 symptoms/problems of hemodialysis patients.

Independent variables are the planned teaching in relation to selected components of HRQoL reinforced by instruction manual on the same topics and the background characteristics of the subject.

3.3   Settings of the study

The study was conducted in the dialysis unit of MGM New Bombay Hospital Vashi, Navi Mumbai and Apex Kidney Care Mulund and Malad in Mumbai.

MGM New Bombay Hospital, Vashi is a multi specialty private Hospital. . The dialysis unit/artificial kidney unit situated on the 1st floor of the hospital, is running since ten years. It is   spacious well equipped with 12 beds and dialysis machines with one bed each reserved for Hepatitis B and Hepatitis C positive cases. Approximately 75 hemodialysis patients are registered there at a time The sister–in–charge of the unit is specially qualified in dialysis nursing. Each bed is provided with curtains for privacy and the unit has a separate waiting area.

The unit is open from 7AM to 10 PM for regular maintenance dialysis patients. The first session starts at 7 AM and completes at 11 AM. Second session is from 12 Noon to 4 PM and the third session is from 5 PM to 9 PM. The dialysis machines are primed, units are cleaned and documentations are completed during the one hour between the sessions. If patients on emergencies call out of schedule they are served/dialyzed at any time irrespective of day or night. Consultant Nephrologists

visit the patients regularly. Doctors are available in the hospital to attend to emergencies.

Apex Kidney Care Dialysis unit at Mulund and Malad are run by a private Trust. They are situated near the respective railway stations. Routines are similar to that of New Bombay Hospital, Vashi but they are stand alone units with laboratory facilities, visited by nephrologists and attended by doctors continuously. Patients requiring emergency admissions are referred to other hospitals. These units have 150 and 75 hemodialysis patients registered at a time. The staff in these units is well qualified.

All the three units cater to all socioeconomic groups. Nurse patient ratio is 1:3. Nurse observes the vital signs, documents and carries out medication orders. The technician maintains the functioning of machine throughout the dialysis process. Both nurses and technicians assist the patients to manage the basic care during the dialysis.

Dialysis patients are scheduled in morning (7 am), noon (12 noon) or evening (5 pm). Most of them are scheduled for 3 times a week - Monday, Wednesday and Friday or Tuesday, Thursday and Saturday. For each patient the day and time is fixed. It is changed if patients demands for any particular reason or at times when machines need to be serviced.

These institutions were selected for the study because of the ease in availability of subjects and the researcher's accessibility and familiarity with the units.

3.4 **Population, sample and sampling technique**

3.4.1 **Population**

The population comprised of adult male and female patients who were on maintenance hemodialysis from March 7, 2009 to July3, 2009. The patients who fulfilled the sampling criteria were selected for the study.

3.4.2 **Inclusion Criteria**

HD patients

- between the ages of 18 to 69 years

- on maintenance or chronic hemodialysis for a minimum period of one month

- who have not undergone kidney transplant operation in the past

- who are not having any other organ failure

- who are not critically ill

- who are willing to participate in the study.

3.4.3 **Exclusion Criteria**

HD patients

- undergoing dialysis for acute conditions

- who are failed transplant operation cases

- who are critically ill

3.4.4 **Sample size**

The sample size of minimum 100 was decided so as to have a fairly large group for higher representation, accurate estimation and for minimal sampling error.

3.4.5 Sampling technique

A convenience sampling technique was used to collect data from 110 patients who met the sampling criteria during the period of data collection. The subjects were selected from three dialysis units as described before.

3.5 Instrument

The instrument used for the for the study was a structured interview schedule consisting of four sub parts (Appendix H)

3.5.1 Development of the instrument

The researcher has developed the tool to elicit the knowledge responses from the participants .The tool used for the study was a structured interview schedule which was developed by the researcher following discussions with nephrologists dealing with hemodialysis patients and referring to various related studies, articles and literature .A qualitative content analysis of selected items from four generic instruments and two kidney disease specific instruments which capture the symptoms/problems of MHD patients was done . These items were found congruent with the prevailing symptoms/problems of the MHD population known to the researcher.

Quality of Life researchers believe that both generic and disease specific instruments should be used to provide the most comprehensive assessment of HRQoL. As a result, it is possible to identify significant areas of patients' lives that have suffered and to help patients focus more accurately on their treatment and self-management efforts[43].

Based on this information the tool was developed including items concerning structure and functions of kidneys, kidney failure and the causes as well as the management of these symptoms/problems and prepared an instruction manual

containing the same information. Basic knowledge of kidneys and kidney failure is necessary to understand the symptoms and management of hemodialysis.

The tool was given to 19 experts for content validity (Appendix B) which include experts from the field of nephrology, nursing education, nursing practice, general education physiotherapy, clinical psychology, dietetics and statistics. Of the 19 experts, only 17 responded. With inputs from these experts and guides the tool was modified and organized under four sub headings.

Part I presents the background characteristics of the sample

Part I A   focuses on demographic characteristics

Part I B   focuses on medical characteristics

Part II presents the knowledge of hemodialysis patients

Part II A presents the knowledge of hemodialysis patient regarding kidneys, kidney failure and its treatment.

Part II B presents the knowledge of hemodialysis patients regarding the causes of symptoms /problems or selected components of HRQoL.

Part III presents the actual HRQoL related to selected components and the practices of hemodialysis patient regarding the management of these symptoms/problems.

Part III A describes the actual HRQoL related to selected components

Part III B describes practices of hemodialysis patients regarding the management of these symptoms/problems or HRQoL.

Part IV   deals with the views of hemodialysis patients about the instruction manual.

The tool was translated into Hindi and Marathi to refer during the interview.

3.5.2   Description of the data collection instrument

Based on the objectives of the study the structured interview schedule consists of following parts.

Part I presents the background characteristics of the sample

Part I A deals with the items of Demographic Characteristics which include 15 items relating to age in years, gender, marital status, type of family, education, care giver and her/his education, occupation-self and care giver, total income per month in rupees, number of family members, source of payment for hemodialysis, place of residence and address and total time spent for dialysis excluding dialysis time per dialysis.

Part I B deals with the items of Medical characteristics which covers 16 items relating to primary cause of kidney disease, co-morbid conditions, medications followed, length of time on dialysis, dialysis schedule followed, serum albumin and hemoglobin level ,general nutritional status, dietary habits, BMI, taking erythropoietin as prescribed, hospitalization in last 30 days, blood transfusion during last 30 days, presence of bleeding from any site, blood flow through vascular access site/minute and inter dialytic weight gain.

Part II presents the assessment of knowledge of hemodialysis patients.

Part II A deals with assessment of knowledge of hemodialysis patients regarding of structure and functions of kidneys, kidney failure and its treatment and include three items assessing knowledge related to structure and functions of kidney, five items assessing knowledge related to renal failure and 13 items assessing knowledge related to dialysis and its management.

Part II B deals with the assessment of knowledge of hemodialysis patients regarding the causes of symptoms/problems or the selected components of Health Related quality of life of hemodialysis patients and includes 12 items.

Part III   deals with the actual Health Related quality of life of hemodialysis patients and practices of hemodialysis patients regarding selected components of Health Related quality of life for the management of these symptoms/problems.

Part III A deals with the actual Health Related quality of life of hemodialysis patients and include one rank order question related to each symptom/problem.

Part III B includes items related to assessment of practices of hemodialysis patients regarding selected components of Health Related quality of life for the management of these symptoms/problems an consists of 12 items with sub items for each symptom/problem.

Part IV assesses the views of hemodialysis patients about the instruction manual.

3.5.3   Scoring and interpretation

The items related to demographic characteristics and medical characteristics were not scored. The items concerning to knowledge were scored converted to percentage and graded and the same was followed for practices but elicited only from those subjects who experienced the particular symptom/problems and are described as below:

0-24 %	Poor = 1
25-39 %	Average = 2
40-54 %	Good = 3
55 -69%	Very Good = 4
More than 70%	Excellent = 5

3.5.4   Reliability (Appendix C)

The reliability of the tool was established using test re test method and analyzed using Cronbach's alpha formula and the scores were entered on sheets.

The reliability of Part II A   -0.96

The reliability of Part II B-   0.93

The reliability of Part III –   Adequate

3.6   Instruction manual

The instruction manual (Appendix I) was developed to teach hemodialysis patients about health related quality of life .The content validity was ascertained by

- o   Reviewing the literature ,research articles, text books and other articles

- o   Discussion with patients and relatives of patient (Hemodialysis) of different dialysis units.

- o   Opinions, suggestions of Nephrologists

- o   Opinions, suggestions of senior nurses in dialysis unit and in nursing education.

- o   The researcher's own experience/observations.

After ascertaining the content validity instruction manual was translated into Marathi and Hindi. The areas included were structure and functions of kidneys, chronic kidney failure and treatment, and the causes as well as the management of the symptoms/problems or selected components affecting HRQoL.

3.7   Pre testing

The tool and the instruction manual were pre-tested on five patients for feasibility and practicability minor modifications were made and were validated again. Patients said that the manual dealt with all the problems/symptoms they faced and the remedial measures for the same.

3.8   Ethical considerations

Ethical approval was obtained from Institutional Ethical Review Committee of Bharati Vidyapeeth Deemed University (Appendix D).

3.9   Pilot Study

The pilot study was conducted on 25 patients from March 2009 to April 2009.It's purpose was to ensure the feasibility and practicability of the design. After obtaining administrative approval, the researcher interviewed the patients of the dialysis unit after recruiting using a screening instrument (Appendix F) and explained the purpose of the study. The consent was obtained on consent form approved by ethical committee of BVDU, Pune and the signature was taken on consent form (Appendix G).

They were assured of confidentiality of their responses and that the information would be used only for research purpose. The teaching was given on an individual basis as they were undergoing dialysis.

The manual was given to them for reference and for further reinforcement of learning. They were told that they would be interviewed after 3-4 weeks. During the intervening period, they were contacted at the dialysis centre to clarify their doubts and to reinforce teaching-learning.   After 3-4-weeks they were again interviewed using the same questionnaire and the responses were recorded.

3.10   Results of the pilot study

Pilot study revealed that the study is feasible and the data was analyzable.

3.11   Data collection

It was decided to collect data from March 2009 to July 2009. Samples fulfilling the inclusion criteria were recruited using a screening instrument and were explained the purpose of the study .On an average 3 to 4 patients were selected per day. They were assured of confidentiality of their responses and that the information would be used only for research purpose. As they were undergoing dialysis pre test

was administered, teaching was given and post test was done as per the following schedule on an individual basis.   .

Day	Session	Activity	Duration
Day 1	Session 1	Introduction, establishing rapport and obtaining consent	30 minutes
Day1or 3	Session2	Pre-test followed by teaching on one to one basis and giving instruction manual in the language of their choice (Marathi, Hindi or English) at the time of leaving the unit.	1 hour to 1hour 15 minutes
Day8or 10	Session 3	Discussion, clarification on instruction manual.	15 minutes
Day 15 to 19	Session 4	Reminder about post-test, discussion	15 minutes
Day 21 to 28	Session 5	Post- test	30 to 45 minutes

Total time spent over three   sessions ranged from two   hours thirty minutes to three hours per sample. The same schedule was continued till a minimum sample size of 100 is reached. At the end of data collection process, complete data was available for 110 samples. Therefore the sample size for the present study is fixed at 110, after due consultation with statistician and guide.

3.12   Data analysis

The data were entered in SPSS (version16). The analysis and findings of the data are presented in the following chapter.

Summary

This chapter deals with the research methodology adopted for the study and includes descriptions of the research approach, research design, settings, sample, sampling technique, data collection instrument and its development, instruction manual, their formation, validity, reliability, proposed plan of data collection and actual data collection.