CHAPTER-III
RESEARCH METHODOLOGY

This chapter contains description of method which was adopted to accomplish to
achieve the set objectives. Research methodology provides guidelines, research steps,
research process & data collection.

It includes:

1. Research approach.
2. Research design
3. Setting of the study.
5. Sample and size.
6. Sampling criteria.
7. Sampling Technique.
8. Description of variables.
13. Ethical consideration.

The present study aims to assess the effectiveness self-management training on Type
2 DM to the patients in terms of KAP.
Figure No: 2 Schematic Representation of Research Methodology.
1. Research approach:-
Quantitative Evaluatory approach was used to determine the effectiveness of self-management Training on Type 2 Diabetes mellitus.

Quantitative Research approach is used to quantify the problem by way of generating numerical data or data that can be transformed into useable statistics. It is used to quantify knowledge, practice, attitudes, opinions, behaviors, and other defined variables – and generalize results from a larger sample population\(^{129}\).

2. Research design: -

Pre-test post-test with control group design was adopted in this study to assess the effectiveness the knowledge, attitude & practice of patients regarding Self-Management on Type 2 Diabetes mellitus.

Pre-test post-test with control group design is a type of true experimental design where test units are randomly allocated to an experimental group and control group. Both groups are measured before and after the experimental group is exposed to a treatment\(^{130}\).

In this study, pre-test was carried out for both Experimental and Control group and individual/Group teaching was administered only to experimental group, eventually Post-test was conducted for both experimental and control group.

**Table No.-2:- Symbolic representation of Research Design**

<table>
<thead>
<tr>
<th>GROUP</th>
<th>SAMPLES</th>
<th>PRE-TEST</th>
<th>INTERVENTIONS</th>
<th>POST-TEST</th>
</tr>
</thead>
<tbody>
<tr>
<td>EXPERIMENTAL</td>
<td>Patients with Type 2 Diabetes mellitus residing at Waghodia taluka.</td>
<td>(O_1) 1st day</td>
<td>X</td>
<td>(O_2) After 2 weeks</td>
</tr>
<tr>
<td>CONTROL</td>
<td>(O_3) 1st day</td>
<td>No Intervention</td>
<td></td>
<td>(O_4) After 2 weeks</td>
</tr>
</tbody>
</table>
KEY -:

$O_1 = \text{It is the First Observation means Assessing pretest knowledge, Attitude and practice regarding self-management of the type 2 diabetic patients among experimental group.}$

$X = \text{Conducted individual/ Group Training to the patients with diabetes mellitus on Self-management training among experimental group.}$

$O_2 = \text{It is the second observation means Assessing posttest knowledge, Attitude and practice regarding self-management of type 2 diabetic patients among experimental group.}$

$O_3 = \text{It is the third observation means Assessing pretest knowledge, Attitude and practice regarding self-management of type 2 diabetic patients among control group.}$

$O_4 = \text{It is fourth observation means Assessing posttest knowledge, Attitude and practice regarding self-Management of type 2 diabetic patients among control group.}$

3. Setting of the study:

The study was conducted in 97 villages of Waghodia Taluka, Gujarat. Waghodia has a total population of 149914, out of which 77319 are male and 72523 are female. Waghodia taluka which comes under Vadodara district has 97 villages. It has four PHCs namely Asoj, Rustampura, Goraj and Waghodia. In the first phase of the study, investigator has conducted a Diabetic demographic survey in order to find the total diabetic population.

In this study all the villages of Waghodia has been classified into four strata in accordance to the Primary health centers & door to door survey was conducted.

Investigator has taken this herculean task of reaching out to all the villages of Waghodia taluka to provide the best of self-management training for the diabetic veterans to the rural and tribal population.
Figure No. 3: Geographical Layout of Waghodia Taluka, District Vadodara.
4. POPULATION

In this study the population includes patients diagnosed with Type 2 diabetes mellitus belonging to geographical area of Waghdia taluka.

![Organogram of the geographical areas of Waghdia Taluka selected for selecting the population of the study.](image)
The diabetic demographic survey was conducted to screen the total Type 2 diabetic patients existing in Waghodia taluka. Demographic survey Proforma was prepared to collect the necessary data. The schedule for survey and road map for easy accessibility to each and every village was prepared. Door to door survey was conducted systematically with a structured demographic survey Performa. Total of 2998 known diabetic patients were ruled out from 97 villages of Waghodia taluka.

5. **SAMPLE AND SAMPLE SIZE:**

Prevalence of adult diabetic population between 31 to 63 years is 1.1% & the sample size was calculated by using the formula \( N = \frac{Z^2 \times p \times q}{d^2} \) Where \( Z = \) (SD score at 99% confidence) is 2.58, \( P = \) (Assumed prevalence of adult diabetic population as per the criteria) is 1.14%, \( q = (1-p) \) 0.9886, \( d = 0.01 \). By using the above formula, the sample size estimated was 750 type-2 Diabetes Mellitus Patients Residing in Waghodia Taluka out of which, 375 in Experimental and 375 in control group were randomly assigned by using computer aided random assignment table.

Table No. -3: Table representing the total accessible samples.

<table>
<thead>
<tr>
<th>Sample Size (750)</th>
<th>Experimental Group</th>
<th>Control Group</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>375</td>
<td></td>
<td>375</td>
<td>750</td>
</tr>
<tr>
<td>Drop out</td>
<td>15</td>
<td>24</td>
<td>39</td>
</tr>
<tr>
<td>Accessible sample</td>
<td><strong>360</strong></td>
<td><strong>351</strong></td>
<td><strong>711</strong></td>
</tr>
</tbody>
</table>

6. **SAMPLING CRITERIA:**

“In the sampling criteria, we specify the characteristics of the population under the study. It has inclusive and exclusive criteria.

**Inclusion Criteria**

- Patients with known Type II diabetes mellitus aged between 30 – 65 years.
- Patients those who are residing in Waghodia taluka.
- Who gave written informed consent to participate in the study

**Exclusion Criteria**

- Patients who have professional qualification in health care services.
- Juvenile & gestational DM patients.
- Diabetic Patients those who were admitted in the hospital with severe complications associated with diabetes mellitus.”
7. **SAMPLING TECHNIQUE:**

**Proportionate Stratified Random Sampling** was used in this study.

The type-2 Diabetic patients were screened all over the Waghdia taluka using a Diabetic survey proforma. Accordingly, the total diabetic patients identified after the demographic survey was 2998 (Juvenile, gestational diabetes and complicated cases were excluded). The investigator segregated the entire population according to the villages. (Total 97 villages) those villages were stratified into 4 as per the PHC’s of Waghdia Taluka i.e. Asoj, Rustampura, Goraj and Waghdia.

**Proportionate Stratified Random Sampling** is a probability sampling technique wherein the researcher divides the entire population into different subgroups or strata, then randomly selects the final subjects proportionally from the different strata.

In this study the sample size of each stratum is made proportionate to the population size of the stratum. Each stratum has the same sampling fraction; here are 4 strata with 365,804,590 and 969 Population sizes respectively. Thus, chose a sampling fraction of ¼ from each stratum.

The **systematic random sampling** was used to select the samples from each stratum i.e every 4th person. The samples of 159, 201,148 and 242 subjects were selected respectively. Therefore the total samples become 750.

In order to classify the samples into experimental & control group, systematic random sampling was used. Odd numbers of the listed samples included into experimental group and even numbers included into control Group. Therefore, 375 samples were included in experimental group and the same numbers of samples were allocated for the control group. Amongthe experimental group, 15 samples were drop outs and 24 from control group among this 29samples have not shown the interest to continue, 4 samples had severe illness and 6 samples were hospitalized. Therefore, the final samples participated in the intervention were 360 in experimental group and 351 in control group. Thus the total samples for the study were 711.
Figure No. - 5: CONSORT FLOW DIAGRAM OF SAMPLING TECHNIQUE

Waghodia (97 villages)

Strata's

Asoj

28 villages

Total number of Diabetic population: 635
Proportionate sample: (23%) (Every 4th Person) = 159

Rustampura

27 villages

Total number of Diabetic population: 804
Proportionate sample: (25%) (Every 4th Person) = 201

Goraj

23 villages

Total number of Diabetic population: 590
Proportionate sample: (25%) (Every 4th Person) = 148

Waghodia

19 villages

Total number of Diabetic population: 969
Proportionate sample: (25%) (Every 4th Person) = 242

Odd Numbers were included into Experimental group & Even numbers included in Control Group.
8. DESCRIPTION OF THE VARIABLES:

“In this study, Variables are the qualities, properties, or characteristics of person, things or situations that change or vary.

The variables under this study are the following,

a) Independent Variable:

In this study, the independent variable is Self-Management Training on Type 2 Diabetes mellitus.

The investigator prepared the overall plan of individual/Group self-management training on the basis of suggestions given by the guide and necessary modifications were made and the teaching plan was finalized.

b) Dependent Variable:

In this study, dependent variable refers to knowledge, Attitude and Practice of diabetic patients regarding self-management on type II diabetes mellitus. Here, the knowledge, attitude and practice represent the outcome of interest that is affected by independent variables.

c) Demographic Variable:

In this study, demographic variables are characteristics or attributes of subjects that are collected to describe the sample such as age group, gender, marital status, area of residence, educational status, occupation, monthly family income, Life style, family history, duration, treatment of Diabetes mellitus, Co-morbid disease, Previous source of health information, self-assessment regarding knowledge of diabetes mellitus”.

9. DEVELOPMENT OF TOOL FOR DATA COLLECTION:

The tool is designed to collect relevant information regarding knowledge, attitude and practice on self-management of type II Diabetes Mellitus.

There were two different parts in the tool in order to explicit the various parameters of the samples.

**Part 1:** Structured Interview Schedule consists of 14 items is prepared to elicit **Personal and clinical characteristics** of diabetic patients.
Part II: This part consists of 3 different questionnaires to assess Knowledge, attitude and Practice.

Section: 1 structured cafeteria questionnaire consists of 20 items to assess the knowledge on self-management of type II Diabetes mellitus.

Section: 2 Structured Likert Scale consists of 18 items to assess the attitude on self-management of type II Diabetes mellitus.

Section: 3 Structured Criteria Checklist consists of 29 items to assess practice on self-management of type II Diabetes mellitus.

Description of tool and scoring method:

I: Demographic Data
   This section deals with the demographic variables. This is the characteristics of the samples. This includes age group, gender, marital status, area of domicile, educational qualification, occupational status, monthly family income, Life style, family history, duration, treatment of Diabetes mellitus, Co-morbid disease, life style practices, Previous source of health information&self-assessment regarding knowledge of diabetes mellitus.

Operational definitions:

Urban: It refers to the samples residing in the geographical area of Waghodia town under Municipal Corporation.

Rural: It refers to the sample residing in the villages of Waghodia Taluka other than Waghodia town.

Illiterate: Sample who seeks help to read or writes the questionnaire and the content during the data collection.

Primary education: The samples those who undergone Early or elementary schooling; I-V standard of education in any language medium.

Secondary education: Middle schooling of any medium of instruction from class IV to X.

Higher secondary education: Those who have completed their 11-12th class examination
**Graduate:** A person who has successfully completed an undergraduate course.

**Medical/Para-medical education:** person who completed any education related to medical or medical related courses: it may be certificate, diploma, degree or post graduate degree.

**Unemployed:** Sample who has no paid job for his education.

**Farming:** Those who are involving in agricultural production.

**Self employed:** Persons earning by doing something by oneself other than agriculture.

**Government Employee:** Those who are employed in government agency and receiving monthly salary.

**Private employee:** Those who are employed in private agency and receiving monthly salary.

**Retired:** Those who are stopped working due to superannuation.

**Life style:** The sample’s pattern of working style it is in terms of physical activity.

**Sedentary worker:** It denotes that the little or less physical activity during their routine job.

**Heavy worker:** It denotes that the Heavy or strenuous physical activity during their routine job.

**Co Morbid disease:** In this study, co morbidity is the presence of one or more additional diseases or disorders co-occurring with Diabetes mellitus such as Hypertension, CCF, Renal Disorder, Anemia, Liver disorder.

**Life style Practices:** It means samples behavior, attitude, interest, values or leisure activity such as exercise, yoga, social activities, alcohol consumption, smoking etc.

**Previous Source of health information:** this denotes area from where samples received the information regarding diabetes mellitus.

**Self Assessment:** It is samples own perception on his knowledge regarding diabetes mellitus in a rating scale of 1to 10.
**Body mass Index:** An approximate measure of whether sample is over or underweight, calculated by dividing their weight in kilograms by the square of their height in meters.

**Part-2:**

**Section1: Structured cafeteria questionnaire consists of 20 items to assess the Knowledge on Self-management of type II Diabetes mellitus.**

The self-developed cafeteria questionnaire is an interview questionnaire that focuses on subjective knowledge on self-management of type II diabetes mellitus. The tool consists of 20 items that would help to screen the knowledge regarding self-management of type II Diabetes mellitus. After the patient has completed the questionnaire the score will be add up. The highest possible total for the whole test would be 90. This would mean the patient circled all the options on all twenty questions. Since the lowest possible score for each question is zero. This would mean the patient has not given answer. If the score is 00-30 the screened level of knowledge is said to be Inadequate, if the score is 31-60 it is considered as moderately adequate and 61-90 is screened as adequate knowledge.

**Table No. -4: Scoring Procedure on knowledge regarding self-management of type II Diabetes mellitus.**

<table>
<thead>
<tr>
<th>Sl. No</th>
<th>Score (range)</th>
<th>Level of Knowledge</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>00-30</td>
<td>Inadequate</td>
</tr>
<tr>
<td>2</td>
<td>31-60</td>
<td>Moderately adequate</td>
</tr>
<tr>
<td>3</td>
<td>61-90</td>
<td>Adequate knowledge</td>
</tr>
</tbody>
</table>

**Section-2: Structured Likert Scale consists of 18 items to assess the attitude on self-management of type II Diabetes mellitus.**

It includes 18 items to assess the attitude of self-management of type II diabetes mellitus the section utilized five point Likert scale to assess the attitude in terms of strongly agree, agree, uncertain, disagree and strongly disagree. The positive statements secures the strongly agree carries a score of five, a score of four for agree, three for uncertain, two for disagree and one for strongly disagree. The reverse is for the negative statements. Out of 18 statements 14 were positive items and 04 were
negative statements under the areas of predisposing factors, care and management of type II diabetes mellitus. If the score is 18-42 the screened level of attitude is said to be poor, if the score is 43-60 it is considered as Average and 61-90 is screened as positive attitude.

Table No.-5: Scoring Procedure on attitude regarding self-management of type II Diabetes mellitus.

<table>
<thead>
<tr>
<th>Sl. No</th>
<th>Score (range )</th>
<th>Level of Attitude</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>61-90</td>
<td>positive attitude</td>
</tr>
<tr>
<td>2</td>
<td>43-60</td>
<td>Average</td>
</tr>
<tr>
<td>3</td>
<td>18-42</td>
<td>Poor</td>
</tr>
</tbody>
</table>

Section-3: Structured Criteria Checklist consists of 29 items to assess practice on self-management of type II Diabetes mellitus.

The tool consists of three areas such as:

1. Self-administration of insulin.
2. Self-monitoring blood glucose level
3. Foot care instructions

The observations were marked under two namenclatures, “yes” and “No”. One mark was assigned to each item if it was yes. The total possible score is 29. If the score is between 00-09 then it is considered as poor practice, if the score is between 10-19, then it is considered as average practice and if the score is 20-29, then it is considered as good practice.

Table No. - 6: Scoring Procedure on Practice regarding self-management of type II Diabetes mellitus.

<table>
<thead>
<tr>
<th>Sl. No</th>
<th>Score (Range )</th>
<th>Level of Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>20-29</td>
<td>Good practice</td>
</tr>
<tr>
<td>2</td>
<td>10-19</td>
<td>Average</td>
</tr>
<tr>
<td>3</td>
<td>00-09</td>
<td>Poor</td>
</tr>
</tbody>
</table>
Content Validity & Reliability of the tool

Content validity of the tool was established by 08 experts comprising of 1 diabetologist, 1 physician, 1 Intensivist, 1 statistician, 1 Health care administrator and 3 were from nursing department.

The experts were requested to give their opinion and suggestions regarding the relevance of the tool for further modification of items, to improve the clarity and content of the items. Initially the tool developed consisted of 18 items on socio-demographic data in which 100% agreement on all items, but suggestions were given to modify and simplify the wording of question 15. The tool consisted of 20 items for knowledge assessment, 18 items Likert scale to assess the attitude and 29 items for observation checklist. Necessary corrections were made on the basis of the suggestions given by the validators. The tool and the content were translated to Gujarati by language experts.

In Part II, section 1, there were 20 structured cafeteria questions to assess the Knowledge on Self-management of type II Diabetes mellitus and experts suggested to rearrange the questions in a sequential order, it was arranged accordingly.

Section 2 was the attitude scale consisted of 18 items and all items had 100% agreement.

Section 3 was the checklist which consists of 29 items on self-management of type II Diabetes mellitus and all the items had 100% agreement. The average time taken to complete the pre-test knowledge, attitude & practice questionnaire was 25-30 minutes, individual training session was 45-60 minutes and post-test was 25-30 minutes.

After the validity of tool, reliability of the instrument was established by administrating to 25 subjects. Reliability of the knowledge questionnaire was found out by using Spearman Brown Prophecy Formula and it was found to be 0.77, which indicated that the tool was reliable and the same formula used for structured Likert scale to assess the attitude i.e. 0.9 hence the scale is found to be reliable.

Procedures performed by patients were observed and recorded at the same time by the investigator. Karl Pearson correlation co-efficient was used to find out linear relationship between the two sets of scores. The reliability of the observation checklist was found out by Spearman – Brown Prophecy Formula and it was found to be 0.78, which indicated that the tool was reliable.
Development of self-management training Module:

The self-management training module was developed for patients with type II diabetes mellitus. It was prepared based on review of literature and discussion with guide.

The content of Self-Management Training on Type 2 Diabetes mellitus includes Introduction, definition, Risk factors, classification, Sign & Symptoms, Diagnostic finding, self management management of diabetes mellitus such as dietary guideline, medication administration, exercise, blood glucose monitoring, foot care and prevention of complication.

Demographic survey of Diabetic patients at Waghodia Taluka

- In-order to study the total diabetic population, Investigator conducted the demographic survey all over 97 villages of Waghodia.
- About 12 volunteers were chosen to conduct door to door survey
- Area map and route map of Waghodia was prepared.
- Systematically assigned the villages to all the volunteers.
- Prepared a demographic survey Performa to collect the necessary data.
- Designed a Data sheet for entering village-wise data.
- Conducted door to door survey and obtained the data.
- The process of demographic survey was between May 2015 to August 2015.

10. PILOT STUDY:

The main aim of pilot study is to assess the feasibility, practicability and assessment of adequacy of measurement.

The duration of pilot study process was from 15\textsuperscript{th} October 2015 to 30\textsuperscript{th} October, 2015. The sample size for pilot study was 25. Purpose of the study was to know the difficulties in collecting data, administration of training, and post test. The informed consent was taken from the subjects prior to the study and obtained their cooperation, after which the tool was administered. On the first day, the pre-test was conducted and simultaneously self-management training was given. The post-test was conducted after 2 weeks by using the same interview schedule. The average time taken to complete the pre-test was 25-30 minutes, individual training session was 45-60 minutes and post-test was 20-25 minutes.
Table No. - 7: PROCESS OF DATA COLLECTION:

<table>
<thead>
<tr>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Phase IV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sample</strong></td>
<td><strong>Tool and technique</strong></td>
<td><strong>Diabetic Demographic Survey</strong></td>
<td><strong>Pre-test</strong></td>
</tr>
<tr>
<td>Type-2 Diabetes mellitus patients residing in Waghodia Taluka. (Experimental Group)</td>
<td>1. Structured Interview Schedule-to assess clinical characteristics 2. Structured cafeteria questionnaire - to assess the knowledge 3. Structured Likert Scale - to assess the attitude 4. Structured Criteria Checklist - to assess practice</td>
<td>Conducted door to door survey in-order to study the total diabetic population, all over 97 villages of Waghodia. About 12 volunteers were chosen to conduct door to door survey Area map and route map of Waghodia was prepared. Prepared a demographic survey Performa to collect the necessary data. Designed a Data sheet for entering village-wise data.</td>
<td>The questionnaire was administered to 711 samples - to assess the existing knowledge, attitude and practice.</td>
</tr>
<tr>
<td>Type-2 Diabetes mellitus patients residing in Waghodia Taluka. (Control Group)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
- **Period of data collection**

  The process of Data collection for the main study was from 15\textsuperscript{th} January 2016 to 30\textsuperscript{th} May 2016.

- **Permission from the samples, informed consent and Rapport building.**

  The research investigator obtained the ethical clearance and formal permission from the samples and informed consent was obtained to conduct the study. Prior to data collection, the investigator familiarized him with the subjects and explained to them the purpose of study. He requested the participants’ full co-operation and assured them the confidentiality of their response.

- **Training for the trainers:**

  The investigator selected 12 voluntary nursing professionals, trained them in the intended subject and collected data from villages of Waghodia taluka. Community survey of Waghodia taluka was done to identify All of them were given training regarding assessing knowledge, attitude & Practice of diabetic patients on self management of type II diabetes mellitus.

- **Classification of Waghodia and route mapping:**

  The investigator segregated the entire population according to the villages. (Total 97 villages) those villages were stratified into 4 as per the PHC’s of Waghodia Taluka i.e. Asoj, Rustampura, Goraj and Waghodia.

- **Pre-Test:**

  The questionnaire was administered to 711 samples in order to assess the existing knowledge, attitude and practice.

- **Intervention:**

  On the same day, the training session was conducted to the samples at their home environment with the help of Demo Kit.
- **Post Test:**

  The post-test was conducted after 2 weeks by using the same tool. The average time taken to complete post-test was 25-30 mts, duration of training program was 45-60 minutes and average time taken for post-test was 20-25 mts.

- **Data Compilation:**

  A data sheet was designed to systematically gather the collected data and compiled for data analysis.

11. **PLAN FOR DATA ANALYSIS:**

   The data was analyzed using descriptive statistics for demographic variables and inferential statistics such as Mann Whitney test to find out the effectiveness of Self-Management training among experimental and control group. Spearman browns prophecy was used to find the correlation between the knowledge and practice. Chi-square test was used to test the association between demographic variables with the mean pre-test level of knowledge, attitude and practice.

12. **CONSIDERATION:-**

   Ethical clearance was obtained from the Sumandeep Vidyapeeth University HRRP department with Ref No: SVIEC/ON/2015/15009 dated 20.01.2015. Written consent was obtained from the samples after explaining the importance of getting self-management training. No financial burden was given to the participants towards the materials used during the intervention. Anonymity and confidentiality of the participants have been maintained during study.

**Summary:**

This chapter deals with the methodology under taken for the study. It includes research approach, research design, and setting of the study, variables, population, sample and sampling technique used for the study, pilot study, data collection procedure, plan for data analysis and ethical consideration.
We were motivated by the co-operation and appreciation of the subjects and their positive response throughout the study. The subjects were very co-operative and showed much interest to keep abreast with diabetic self management training.