CHAPTER III

METHODOLOGY

Research Approach

An evaluative approach was adopted to assess the effectiveness of structured teaching programme on knowledge and practice of diabetes patients on lifestyle modification.

Research design

The research design chosen for the present study was pre experimental with single group pre- post-test design. By using non probability, convenient sample, 500 diabetic type 2 patients were selected to assess the effectiveness of structured teaching programme.

<table>
<thead>
<tr>
<th>Pre-test</th>
<th>Treatment</th>
<th>Post-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge and practice</td>
<td>Structured teaching</td>
<td>Knowledge and practice</td>
</tr>
<tr>
<td>test</td>
<td>Module</td>
<td>test</td>
</tr>
<tr>
<td>((0_1))</td>
<td>((X))</td>
<td>((0_2))</td>
</tr>
</tbody>
</table>

**Figure 2: Schematic representation of Research Design.**

The symbols are described as under:

- \(O_1\) – Refers to Pre-test measures of knowledge & practice of subjects
- \(O_2\) – Refers to post-test measures of knowledge & practice of subjects
- \(X\): Structured Teaching Module on lifestyle modification of diabetes patients.
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Variables under study

Independent Variable (I.V.)

- Structured teaching programme on Diabetes Lifestyle Modification.

Dependent Variable (D.V.)

- Knowledge and practice of life style modification of diabetes patients.

Attributed Variable (A.V.)

Demographic characteristics, age, gender, marital status, education, religion, type of family, residence, family income, food habits, smoking, alcohol consumption, duration of diabetes, type of medication prescribed, past history of hospitalization.

Setting of the study

Kempegowda Institute of Medical Sciences Hospital and Research Center, located in V.V.Puram, Bangalore, having an 830 bed capacity and consisting of all specialties, with 174 medical inpatient bed and 203 surgical beds.

Population of the study

Diabetes type 2 patients admitted to Kempegowda Institute of Medical Sciences Hospital and Research Center, Bangalore.
Sample and Sampling technique

Sample of the study comprised of 500 diabetic type 2 patients, who were admitted in Kempegowda Institute of Medical Sciences Hospital and Research Center, who met the inclusion criteria.

Convenient sampling method was employed, to select the subjects who were admitted with type 2 diabetes mellitus in Kempegowda Institute of Medical Sciences Hospital and Research Center, Bangalore.

Criteria for selection of sample

**Inclusion criteria:** Diabetes Type 2 patients,

- admitted in Kempegowda Institute of Medical Sciences Hospital and Research Center, Bangalore.
- admitted with comorbid disease condition.
- willing to participate in the study.

**Exclusion criteria:** Diabetes type 2 patients

- who are admitted to acute care areas.
Ethical consideration

Prior permission has been obtained from the concerned authorities of Kempegowda Institute of Medical Sciences Hospital, and research center, informed consent obtained from subjects of the study.

Selection and Development of Instrument

Data collection tool or instruments are the vehicle that could best obtain the data pertinent to the study and at the same time adds to the body of knowledge in the discipline.

Selection of the tool

The tool used for this study was structured interview schedule on diabetes lifestyle modification: knowledge and practice.

Development of the tool

In order to develop the said tool, the following activities were conducted.

- Literature review
- Consultation and discussion with nursing experts.
- Personal experience and discussion with colleagues.

A blueprint was prepared prior to the construction of the questionnaire which showed the distribution of items according to the content area. Following that, items for the interview schedule were developed, and put in a logical order.
Structured interview schedule

The instrument was developed after the discussion with expert in the field, guide, co-guide, research advisory committee members, and search for developing instruments was also done through internet, journals, books and other materials. The Instruments are divided into:

Part I: Socio Demographic Profile which consists of 24 items, like, age, gender, marital status, education, religion, type of family, residence, family income, food habits, smoking, alcohol consumption, duration of diabetes, type of medication prescribed, past history of hospitalization. (Appendix: 1)

Part II: Structured Interview Schedule on diabetes lifestyle modification knowledge consisting of 64 items. (Appendix: 2)

Section includes the following:

- Diabetes and its Knowledge domain -13 statements
- Monitoring blood glucose- 7 statements
- Diet adherence -14 statements
- Medication practice-8 statements
- Exercise- 9 statements
- Foot care practice-13 statements

Each question had 4 options out of which one option was appropriate, each correct answer carried a score of “one” (1), while each wrong answer was given “Zero” (0) score.
Part III: Structured interview schedule on diabetes lifestyle practice consisting of 87 items on: (Appendix: 3)

- Diabetes practice domain - 10 statements
- Monitoring blood glucose - 7 statements
- Diet adherence - 12 statements.
- Medication practice - 10 statements
- Exercise - 11 statements
- Foot care practice - 12 statements
- Hypoglycemia - 8 statements
- Driving and traveling, eye care and sick day management - 13 statements
- Management of complications - 4 statements.

Each question has two options: (“yes” or “no”); each correct answer had a score of “one” (1), while each wrong answer was given a “zero” (0) score.

Content Validity of the tool

Content validity of the tool was established after consulting experts in nursing, the guide, co-guide, and statistician, research advisory committee members and diabetologists. The suggestions given by them were incorporated and later, tool was edited by English language experts and translated into Kannada language by experts and back translation, without changing the meaning of the content of the tool. Thus, it was found to be valid and suitable.
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Pre-testing of the tool

Pre-testing of the tool was done on a sample of 50 subjects who were similar in characteristics to those of the subjects under study, to check the clarity of the items, their feasibility and practicability.

Reliability of the tool

The reliability of the tool was established by taking 50 type 2 diabetes patients. Split half method, using Brown Prophecy formula was adopted. The reliability “r” for the knowledge tool was found to be 0.9382, (P < 0.001) and reliability of the practice tool was found to be 0.8584. (P < 0.001) which was statistically significant and thus the tool was found to be reliable for the study.

The study subject coped considerable well with the interview/questionnaires, and not faced any difficulties, they also instructed to know the calories of the different food items and techniques of exercise and adhere to the all domains of diabetes life style modification in the study.

Development of Structured Teaching Programme

Effort was made to develop structured teaching programme, based on life style modification of diabetes patient’s knowledge and practice for the following components:

- Domain of diabetes knowledge and practice.
- Monitoring blood glucose.
- Diet adherence.
- Medication practice.
- Exercise.
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- Foot care practice.
- Hypoglycemia.
- Driving and traveling, eye care and sick day management
- Management of complication.

The above teaching programme was developed after extensive review of literature in addition to a series of consultation with experts in the field. Randomly a few patients suffering from diabetes mellitus were also interviewed in order to know their needs regarding the knowledge, and practice area concerning to diabetes. This helped the investigator to appropriately develop teaching programme for the study subject.

While preparing the teaching programme, simplicity of language and content coverage of the type of diabetes mellitus were taken into consideration. Care was taken to avoid technical words. (Appendix: 4)

**Content validity of the structured teaching programme**

Content validity of the structured teaching programme was validated by a few experts in the field of nursing and medicine; their suggestions were incorporated in finalizing the structured teaching programme. The structured teaching programme was translated into local vernacular Kannada by an expert.

**Pilot Study**

Pilot study was conducted in Bidadi Health center, which is situated close to Bangalore, 50 type 2 diabetes patients who fulfilled the inclusion criteria were recruited
for pilot study to test the feasibility of the research tool. The data was subjected for statistical analysis and the results indicated that, Pre-test and post-test knowledge score were found to be significant for the knowledge domain under consideration. The overall enhancement in the score found in the entire knowledge domain, and statistical significance, indicated the effectiveness of structured teaching programme on lifestyle modification. The practice score between Pre-test and post-test found to be statistically significant.

The subjects who were included in pilot study, were excluded from the main study. The results revealed that the structured teaching programme on lifestyle modification was effective in gaining knowledge and practice by diabetes patients. This revealed that the study is feasible to conduct.

The following observation was made:

- Time taken for administering the tools: on an average 45 minutes.
- Time taken for teaching: 45-50 minutes per session/ per group
- Subjects were comfortable in understanding the questions asked.

Procedure for Data Collection

Formal written permission was obtained from the Medical Superintendent of Kempegowda Institute of Medical Sciences Hospital and Research Center, Bangalore, Karnataka. The study was conducted with 550 diabetes patients’ selected, taking into consideration a possible 10% dropout rate, by convenient sampling technique. Informed consent was obtained from the subjects who were participated in the study. Self
introduction was given by investigator, nature and the purpose of conducting the study was explained.

The data collection was carried out using pre designed questionnaires which included the following sections:

**Section 1:** Socio demographic profile.

**Section 2:** Structured interview schedule on diabetes life style modification knowledge.

**Section 3:** Structured interview schedule on life style modification practices.

**Step 1: Pre-test**

- Structured interview schedule, as mentioned in the section I, II, and III were administered individually one after another in different wards (male medical ward, female medical ward, male surgical ward and female surgical ward) and data was collected.

**Step 2: Administration of Structured Teaching Programme**

- Structured teaching programme was administered for all the patients who participated in the Pre-test, by requesting them to assemble in a seminar room provided by hospital. The content of structured teaching programme was explained in the local language, supported by pictures, photographs and discussion.

- Structured teaching programme administered to those patients who were scheduled to be discharged on the same day of Pre-test
The structured teaching programme was administered in batches, 2 batches in a week, each batch consisting of 12-15 subjects.

Time taken for structured teaching programme for each batch was 45 to 50 minutes.

In this session importance was given to exploring the possibilities for taking self care, and the involvement of family members, recognition of non compliance of self care etc. The focus was on adherence to all components related to self care and not only on monitoring of blood sugar or medication; efforts were taken to make the patients understand the importance of lifestyle changes. Emphasis was given on encouraging the patients to develop required skills and not to give excuses or reasons for non adherence. The objective was to make the patients understand self care techniques so as to avoid complications, with an added emphasis on positive changes in lifestyle.

**Step 3: Post-test**

- After one week of administration of structured teaching programme, post-test was conducted using schedule on diabetes lifestyle modifications in knowledge and practice.
- Total data collection took 25 weeks, for the Pre-test and post-test were held over 22 weeks.

**Drop out:** considering a 10% drop out rate, additional 50 subjects were included. During post-test 50 patients were dropped (those who were not available during post-test).

While administering post-test, efforts were taken to establish rapport with patients and discussed the problems perceived by the patients.
Data analysis and Interpretation

Analysis of data

Data collected were edited, tabulated and interpreted by using descriptive and inferential statistics based on the formulated objectives of the study. Demographic characteristics were analyzed by generating univariate and bivariate frequency tables, and the measures of central tendency such as mean, and standard deviation were generated.

The mean score of Pre-test and post-test were compared using paired t-test. The associations between the knowledge and practice scores with selected demographic variables were carried out using chi square test. Any ‘p’ value less than or equal to 0.05 was considered to be statistically significant. The correlation between knowledge and practice was studied using Karl Pearson’s co efficient ‘r’

The above analysis focus on testing the difference between pre and post test knowledge level not on their practice, the reported knowledge on practice by the subject were analyzed.