Methodology

Methodology is a plan and procedure for carrying out the research. It refers to research techniques for obtaining valid information. It is the philosophy on which research is based. Methodology aims to obtain knowledge, based on empirical observations and logical reasoning. This chapter deals with a detailed description of the methods and supporting references used in the present investigation on the “Development of an intervention module for management of type 2 diabetes mellitus”.

Diabetes mellitus is a major health problem the world over, including the developing countries. The rapid growth in its incidence poses economic and social implications globally. It has been well documented that diabetic patients have an increased susceptibility to both microvascular and macrovascular complications and a high mortality rate and morbidity. Therefore effective strategies for diabetic management are highly imperative. Patient education, as an integral component of the therapeutic package for diabetic control, acquires special significance in this context (Golay et al., 2003). The aim of diabetes education is to bring about attitudinal changes and improvement in knowledge and care skills and enable the diabetics to become self-sufficient in taking day to day care of themselves.

Considering these factors the methodology of the present research has been designed to include the following phases.
Chapter 3

3.1. Locale of the study

Diabetic patients are increasing disproportionately in India due to rapid transition of lifestyle from traditional to westernized and urbanized culture. Prevalence of diabetes in several parts of India has shown a fast increasing trend in the past 15 years. Specifically, Kerala the southernmost State of India claims to have the highest number of diabetic patients and is often referred to as the diabetic capital of India. According to Soman (2007) the prevalence of Type 2 diabetes, in rural Kerala, is similar to or higher than that reported from urban India, which is quite disturbing. But unfortunately the State of Kerala has not yet taken a serious note of the magnitude of this problem or its developmental consequences.

Among the 14 districts of Kerala, Kannur is located in the northern region. It is a beautiful miniature of the picturesque State of Kerala and is the fourth biggest urban agglomeration in the State after Kochi, Thiruvananthapuram and Kozhikode.
As far as the epidemiology of diabetes is concerned a few studies have been reported from the southern parts of Kerala, mainly Thiruvananthapuram and Ernakulam (Kesavadev, 2007; 2006). Kannur, however, is a virgin area in terms of the present topic of research. That is why it has been selected as the study area. Fig.1 presents the location map of Kannur district.
3.2. Sample selection

The success of any study depends on the careful selection of the sample. Sample can be defined as a subset or portion of the total population (Singh, 2001). According to Gupta (2003) sampling is simply the process of learning about a population on the basis of a sample drawn from it. Under this, a small group of the universe is taken to represent the whole mass and the results are drawn from it. It is a method to conduct a practically applicable social investigation.

In the present study purposive random sampling method was adopted to select the sample required for the study. In this technique, the researcher purposely selects the subjects, who are in his/her judgment about some appropriate characteristic required of the sample members, who are thought to be relevant to the research topic and who are easily available to him (Ahuja, 2005). A total of 300 type 2 diabetic patients (150 male and 150 female), were drawn from three specialty hospitals of Kannur such as Christuraja Hospital, Thokkilangady, Indira Gandhi Co-operative Hospital, Thalassery and Dia Care Hospital, Kannur.

Geographical coverage, availability of diabetic clinics and the sample population from different strata of the community in the hospitals, accessibility and willingness of the sample, co-operation on the part of physicians and hospital authorities were some of the criteria considered during the selection of hospitals.

A sample size of 300 diabetic patients were randomly selected from the above three hospitals including 150 men and 150 women.

Inclusion and exclusion criteria

The selected subjects were patients who had type 2 diabetes diagnosed by a physician and were undergoing follow-up care and treatment in the above selected
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hospitals. These patients were above 25 years of age and were willing to cooperate with the study. Whereas patients who were pregnant or with type 1 diabetes or with severe hearing and visual impairment or psychosis problem and other serious complications like insulin pump users were excluded from the present study.

3.3. Tools and techniques of data collection

Appropriate tools and techniques acquire tremendous importance in a research process. However the selection of tools and techniques, solely depends on the type, nature and characteristics of data to be procured.

In the present study the data collection has been done in two phases.

3.3.1. Phase I: Collection of baseline information

Baseline information forms the basis for obtaining a suitable subject, planning an appropriate intervention programme to address the issue and finally to evaluate the effectiveness of the programme after intervention.

Tools and techniques to collect baseline data

Accuracy and credibility of baseline information is of utmost importance as it is the basis on which the intervention is planned and executed. Personal interview method was adopted in investigation as it provides ample opportunity to interact with the sample population, enabling the researcher to collect relevant inputs and to clarify the doubts of the subjects during the different phases of research. It also offers possibility to collect additional information if required through personal observation.

Interview method, according to Kothari (2001), is a suitable tool to collect the required data as it proceeds systematically and enables to record the
information quickly. The information obtained by this method is likely to be more accurate because the enumerator can clear up the doubts of informants while interviewing them (Singh, 1997).

An interview schedule was often used as an instrument or a tool to gather the relevant data with utmost accuracy and appropriateness. As stated by Krishnaswamy (2004) a schedule is referred as a research tool when it is used for interviewing. It is a performa containing a set of structured questions in which answers are normally recorded by the interviewer himself in a face to face situation with the respondents (Ahuja, 2005; Thanulingam, 2000; Reddy et al., 1999).

So development of an interview schedule was the first step initiated towards collection of baseline data. Questions were framed to cover the multifarious aspects of diabetic subject’s viz. socioeconomic characteristics, anthropometric parameters, clinical profile, food habits and dietary practices, lifestyle factors and medical monitoring of diabetes.

A detailed schedule was thus designed and subjected to screening by a group of eight experts including two nutritionists, two dieticians, two diabetologists and two general physicians for accuracy and effectiveness. The schedule was further modified incorporating the suggestions of the experts and pilot tested on a comparable sample of 20 diabetic subjects who were not included in the actual study. The schedule was eventually finalised after incorporating necessary corrections. A copy of the final schedule is given in Appendix-I.

Data collection

Creating a good rapport and a feeling of confidence among the respondents are essential prerequisites for the successful data collection. Concurrence from the practicing doctors and authorities of the hospitals were obtained to have a
leisurely casual interaction with the targeted subjects so as to familiarise with and to orient them on the purpose of the study and the need for obtaining reliable data. Advance intimation on the date and probable time of visit for the collection of actual data was also considered for the smooth conduct of the study.

The investigator personally interviewed all the 300 subjects. A casual and informal approach was followed, allowing the interviewee to interact freely and confidently. The information thus gained was recorded in the structured pretested schedule by the investigator.

Following the same protocol, relevant data, pertaining to specific variables considered under the present study has been procured.

**Background information**

Background information on diabetics and diabetes was collected using the interview schedule. Socioeconomic status (SES) and its constituent elements are well accepted as determinants of health. As far as diabetes is concerned its prevalence among the low income population is two times more compared to wealthy population (Stelmach et al., 2005). Lifestyle and environmental factors, rapid urbanisation and globalisation in South Asian countries promoted mechanisation, which led to sedentary living. This factor coupled with increased use of tobacco and increased intake of calories and fat, lead to increases in weight, blood glucose level, blood pressure, and an unfavourable lipid profiles (Srinath et al., 2005).

The variables which are suggestive as the potential confounding factors of diabetes such as age (Choi and Shi, 2001), gender (Ramachandran et al., 2001), religion, educational level (Haffner et al., 1991), income (Ramachandran et al., 2002) and occupational status (Pradeepa et al., 2002) were reckoned in the study. Other information elicited includes a brief history of diabetes and causative
factors, complications and co-morbidities bothering the subjects and treatment modalities adopted by them.

Similarly information on lifestyle and personal habits of the sample, including physical inactivity (Laaksonen et al., 2005), alcoholism (Hodge et al., 2006; Ajani et al., 2000), smoking (Willi et al., 2007; Foy et al., 2005; Patja et al., 2005) and stress (Golden, 2007; Jacobson et al., 1997); all proved to have a role on the incidence of diabetes, were also investigated by means of the personal interview method.

**Anthropometric profile of diabetics**

Nutritional anthropometry is a measurement of human body at various ages and levels of nutritional status and it is based on the concept that appropriate measurements should reflect any morphological variations occurring due to a significant functional physiological change (Rao and Vijayaraghavan, 2003). The anthropometric measurements, to study the associated risk of obesity, which are also the positive confounding factor for diabetes were considered in the present study. It includes height, weight, body mass index, waist and hip measurements (Appendix-I). The entire 300 sample (150 male and 150 female diabetics) were covered by anthropometry.

**Weight**

Weight is the key anthropometric measurement (Jelliffe, 1966) and is a sensitive indicator of obesity (Venkatalakshmi and Peramma, 2000). Importance and reliability of weight as a measure to assess nutritional status was also emphasized by Bamji (2003) and Rolfs and Whitney (2002).

Body weight was measured using a portable bathroom weighing scale with the subject standing on the scale with head erect, feet about 15 cm apart,
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- distributing weight on each leg. Subjects were instructed to wear minimal outerwear (as culturally appropriate) and were bare footed while they were weighed. They were asked to remain stationary on the scale without touching any objects until an accurate measurement was taken. The body weight measurement was recorded to the nearest 0.01 kilograms.

**Height**

The height of the individual is influenced both by genetic (hereditary) and environmental factors. The maximum growth potential of an individual is decided by hereditary factors. Among the environmental factors, the most important ones are nutrition and morbidity, which determine the extent of influence of genetic potential (Rao and Vijayaraghavan, 2003).

Height was measured using a non-stretchable tape (to the nearest 0.1 cm) with the subject in an erect position against a vertical surface and the head positioned so that the top of the external auditory meatus was in level with the inferior margin of the bony orbit. Subjects were asked to remove their shoes and stand erect against the wall. Their height measurement was recorded in centimeters.

**Body Mass Index**

Body Mass Index (BMI) is an excellent indicator of the nutritional status of a person (Hubbard, 2000) and also to the extent of prevalence of overweight/obesity. Body Mass Index (BMI) was computed using the formula given by Garrow (1987).

\[
\text{BMI} = \frac{\text{weight (kg)}}{\text{height (m)}^2}
\]

The clinical guidelines given by National Institute of Health (NIH, 1998) and Indian Consensus Group (1998) for the identification, evaluation, and
treatment of overweight and obesity in adults has defined overweight as BMI of 25 to 29.9 and obesity as a BMI of at least 30. But WHO Regional Report (2000) has recommended different ranges for classifying overweight and obesity for population in the Asia Pacific Region. This is on the basis of the fact that increase in health related risk factors and co-morbidities associated with obesity occur at a lower BMI in Asian population than in other ethnic groups. So the lower cut-off points for overweight and obesity for Asians were identified, as BMI greater than 23 and BMI greater than 25 respectively.

The cut-off point as suggested by WHO Regional Report (2000) was used in the present study which is given in Table 2.

<table>
<thead>
<tr>
<th>BMI range</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI &lt; 18.5</td>
<td>Underweight</td>
</tr>
<tr>
<td>BMI 18.5 – 20.0</td>
<td>Low but normal weight</td>
</tr>
<tr>
<td>BMI 20.0 – 23.0</td>
<td>Normal weight</td>
</tr>
<tr>
<td>BMI 23.0 – 25.0</td>
<td>Overweight</td>
</tr>
<tr>
<td>BMI &gt; 25.0</td>
<td>Obese</td>
</tr>
</tbody>
</table>

Waist-Hip ratio

It has been shown that the BMI used along with the Waist-Hip Ratio (WHR) is better in predicting risk for many of the serious disorders like diabetes, high blood pressure, lipid disorders and atherosclerosis leading to heart attacks and strokes etc. The girth measurement technique was adopted from WHO report (Helsing, 1998). Waist circumference was measured by using a non-stretchable measuring tape. Measurement of waist circumference was taken, at the narrowest point of the patient’s torso in the standing position. Hip-girth was measured with the subject in the standing position, with both feet together, at the level of the
greater torchanters. When the greater torchanters are not palpable, then the measurement was taken at the level of the largest horizontal girth around the buttocks (Fig.2). Waist to hip ratio was calculated using the formula given below.

\[
\text{Waist-Hip ratio} = \frac{\text{Waist circumference (cm)}}{\text{Hip circumference (cm)}}
\]

The waist circumference recommended by WHO (James, 2005) for Asians was less than 90 cm for men and 80 cm for women. The waist-hip ratio (WHR), as suggested by IDF, (2006) and Willet et al. (1999) were less than 0.95 in males and less than 0.80 in females. These measurements were used in the present study as standards for the comparison of data.

Superiority of waist circumference to be the best overall predictor of abdominal visceral obesity in a cross sectional study of 458 women, as against waist-hip ratio was reported by Rankinen et al. (1999).

Clinical screening of diabetics

Clinical screening of all the subjects (n=300) was done with the help of physicians in the respective hospitals. Separate clinical assessment schedule developed for the purpose was used to collect clinical and biochemical data. The content of assessment schedule, prepared and screened by the same panel of eight
experts, (Appendix-I), started with an appropriation of the case history, diagnosis of incidents of diabetes, signs and symptoms. Also provision was available in the schedule to report on the subjects’ own medical history, and associated complications as suggested by many researchers, like heart disease (Mohan et al., 2001), hypertension (Fuller et al., 1983) and familial aggregation (Cugati et al., 2007; Knowler et al., 1981).

The information on the clinical and biochemical status of the diabetic patients which was already available in the hospital was also made use of, while filling up the schedule. For diagnostic purposes the reference values suggested by ICMR were used. Systolic and diastolic blood pressure of the entire sample was recorded using sphygmomanometer. Measurements were recorded, with the subject in a sitting posture, relaxed and with right arm resting on a table. Fasting blood glucose level was also obtained from the entire sample (n=300).

**Dietary habits and practices**

A diet survey to study the dietary practices and food frequency and consumption pattern of the subjects was conducted on all subjects (n=300). According to Thimmayamma and Rao (2003) precise information on food consumption pattern of people is required for assessing their nutritional status and also for elucidating the relationship of nutrient intakes with incidence of any degenerative health problems, such as diabetes, CVD and the like due to surplus or deficit intake of nutrients. In the present investigation the association between diet and diabetes was studied by collecting relevant information on dietary practices, food habits, meal pattern, nibbling between meals, food consumption from eateries outside home, use of cooking oil, preference for fast food and junk food (Appendix-I).
3.3.2. Phase II: Development and evaluation of an educational module.

Diabetes education is the cornerstone of effective diabetes care (Hogan et al., 2003). Technology can assist with the provision of tailored and personalized education, feedback, and goal setting, thereby facilitating patient centric care. Patient education should be comprehensive in scope, flexible in content, responsive to an individual’s clinical and psychological needs, and adaptable to their socioeconomic and cultural background.

According to Balas et al. (2004; 1998) computerised knowledge management and education can form an important component of quality diabetes care. According to Najjar (1996) computer based multimedia presentation and interactivity helps people to learn information more rapidly and retention of the knowledge over time than traditional classroom lectures and talks. So the intervention module for the target population on diabetic education was developed as power point presentation.

Planning and development of module

This education programme was aimed to promote better self-care and management of diabetes, giving due emphasis on key health messages for the subject population about diet, physical activities and risk factors related to type 2 diabetes and its complications. A detailed care plan for diabetes was therefore generated. This interactive multimedia package comprised of various sub-modules, each of which covered different aspects of diabetes. Messages were carefully selected, tailored and presented. The development of the package included the following steps.
Chapter 3

Setting objectives

The situational analysis done by way of baseline data collection among the subjects of study brought about clearly the nature and intensity of the problem, strength and weakness of prevailing self-care management of diabetes, lifestyle and other risk factors and complications requiring immediate attention.

Considering the above factors the objectives of the educational package has been set and the various components of this need-oriented package on diabetic management was finalised.

The specific objectives of the package included:

- To create awareness and to stress the significance of self-care management in diabetes.
- To emphasis the importance of medical monitoring and prevention and control of co-morbidities and complications in diabetes.
- To build awareness on the causes/risk factors of diabetes.
- To equip the target group with accurate up-to-date and appropriate information tailored to suit the day-to-day management of diabetes.
- Confidence building to bring-in necessary modifications in lifestyle with respect to diet, exercise and stress alleviation.

Procuring relevant messages and materials

The first step in the development of the educational package (power point) consisted of scripting education programme on diabetes mellitus, concepts and management and integrating them towards developing an interactive package. Numerous pictures related to diabetes mellitus were collected from books, journals, pamphlets, websites, and materials from diabetologists. Information collected from the literature was so schemed to suit the target group.
The key components of the proposed programme are based on diabetes and lifestyle, nutrition and fitness (Sirichakwal and Sranacharoenpong, 2008). The contents of the sessions included information on the pathophysiology of diabetes, the role of inheritance and environment, education in self blood-glucose monitoring, the importance of physical activity, healthy diet, weight loss, medication, and smoking cessation and the late complications such as hypertension, cardiovascular disease, neuropathy and nephropathy.

The empowerment approach to diabetes education involves patient collaboration and seeks to increase the patients' knowledge and self-awareness, which enable them to take charge of their own health, diabetes self-management (Funnell et al., 1991). After collecting the resource material, script was prepared in a lively, artistic and creative manner, in both the languages English and the regional vernacular (Malayalam). Care was also taken to keep the terminology of the script simple, to suit the target group.

**Development of software package**

After the script preparation, each slide was designed in power point with apt colour, font, picture and charts and finally custom animated. These slides gave details about how diabetes affects eye, heart, kidney, nerves with the help of photographs. The treatment required after diagnosis was also included.

On the whole 153 slides were developed. Education module was designed as three parts, one complementing the other. Each part of a module had a clear introduction and conclusion, allowing learners to divide each section of module into several self-contained modules in a given learning situation. The sequence of presentation was as follows:

Section 1. Introduction and overview of the diabetes, diagnosis and symptoms
Chapter 3

Section 2. Risk factors, complications and its symptoms related to diabetes, smoking and alcohol.

Section 3. Management of diabetes by diet, exercise, yoga, medication and stress management.

Each section of the educational package was planned for a span of one and a half hours. In addition to the software package, complimentary learning materials like clippings of short films, songs, brochure, charts, demonstrations, printed materials and hand outs providing brief picture of diabetes and its management were used to reiterate the messages, attract attention and stimulate and sustain interest in the learning process.

**Reviewing of software package**

Multimedia presentation gets more attention from the audience than conventional teaching methods. However, reviewing of such packages by experts and beneficiaries ensures overall acceptability, suitability and effectiveness.

The newly developed education module was reviewed by the same panel of experts of eight members who reviewed the interview schedule. Along with them representation of three members from target population who were not included in the feasibility testing of the educational package were also included. The package was reviewed for its content validity, quality, coverage, clarity, communicability, consistency, suitability and the overall approach to the problem situation. Suggestions were solicited so as to effect further improvement of the package. A copy of the software package (CD) thus developed and modified is given in Appendix-II. A checklist for rating of the package was also developed and screened by the same panel (Appendix- III). The copy of learning materials like brochure and recipes given in Appendix-IV and V respectively, as complimentary learning aids used along with the software package.
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Educational intervention

The goal of diabetes education was to optimize blood glucose control, prevent chronic and potentially life threatening complications, and to optimize quality of life, while keeping the treatment cost effective. Incidentally training and education with assured quality is not presently available to those who need, though it is an integral part of diabetic self-care and management. People living with diabetes need to play a crucial role in managing their problems on a day-to-day basis, so self-care support was the main thrust in the present package on diabetes education.

Study setting and target group

Study setting

Identification of location/centre for conducting educational intervention was the first assignment in this respect. One among the three hospitals, where the preliminary research (collection of baseline data) has been conducted, was selected for the purpose, by considering the following:

- A centre visited by maximum number of diabetic patients
- Availability of patients from all strata of the community
- Support and cooperation of the diabetologists in the hospital
- Easy accessibility and infrastructure facilities for conducting the programme.

Dia-Care Hospital, Kannur, fulfilling the above criteria, formed the venue for educational intervention.

Target Group

A sub-sample of 70 diabetic subjects was selected from the total sample of 100 included in the preliminary research conducted in Dia-Care Hospital, based
on their interest and willingness to cooperate with the study. Then the 70 subjects were divided into two groups (control and experimental) with 35 members each by drawing lots.

The members of the experimental group were met individually and were given a detailed picture of the conduct of the study, explained their role as participants for the successful completion of research work including regular attendance, acquiring and practicing of the ideas and information imparted through the programme. Out of 35 subjects in the experimental group only 33 patients readily agreed to these and gave their consent. So total subjects for the intervention programme was 68, including 35 and 33 subjects respectively of control and experimental groups.

*Programme execution*

The educational intervention was conducted as per schedule, once in a fortnight for a duration of three months. Apart from this, a few special demonstration sessions were given on hypoglycemic and low fat menu preparation, early detection of complications and routine physical exercise as a part of self-care management of diabetes. Special counselling sessions were conducted addressing the individual needs of patients to build self confidence so as to initiate lifestyle changes. Thus the ultimate object of the educational intervention being to equip the participants with necessary knowledge and skills and to achieve gradual but sustaining behavioural modifications, much care was taken to provide evidence based information. Plates 1 to 5 presents the different stages of the education programme conducted.
Methodology

Collection of background information

Anthropometric assessment

Plate: 1. Data collection
Plate: 2. Glimpses of educational programme
Plate: 3. Glimpses of educational programme
Recipes for diabetic patients

Plate: 4. Food demonstration
Plate: 5. Follow-up discussion
Chapter 3

The members of control group were not allowed to attend any of the sessions or individual counselling arranged in connection with education programme.

The participants were also given face to face consultation session lasting for 10 to 15 minutes after each educational session on the following aspects.

1. Diet counseling was given mainly on the modification of the existing dietary pattern of individual participants. For which the diet records were collected and its merits and limitations were explained. Cooking demonstrations and distribution of recipes also formed part of this diet counselling.

2. Individual guidance and exercise training was also given to the subjects for increasing the overall level of physical activity at least 30 minutes per day for a minimum of three days per week (as per the guidelines recommended by Nelson et al. (2007)).

3. Participants were encouraged to set an intermediary goal setting for themselves and a plan of actions to achieve this. Instead of an abstract goal a practical goal must be set in increasing fibre intake. (Eg. eat a slice of bread with vegetable, for breakfast or mixed chapatti made of wheat with spinach instead of chappathi alone).

4. Weight monitoring on regular basis with a target of weight reduction at the rate of ½ to 1 Kg per week for overweight and obese patients.

5. Routine laboratory assessment was also conducted prior to and at the end of the intervention.

6. Since the whole family was part of the behavioral modification programme the spouses were also invited to the education session so that they could be informed of the issues and to aid the subjects in the drive.
**Evaluation of the education programme**

Evaluation is a process by which practice can be justified. Evaluation can be used to assess learning, to improve the learning content, communication methodology, assess the viability of any programme and justify the expenditure in terms of money, time and energy. For diabetes educators, evaluation forms an integral part of programme plan. Teaching should be evaluated both at the individual and programme level. On the individual level to assess what the learner had learned to make the behavioural changes, and at the programme level, if the programmes met with the needs of the participants (DH, 2005).

In the present study the main purpose of evaluation was to explore changes in knowledge and practices of the selected subjects (n=33) and also their approach to deal with the Diabetic Management problems.

Different types of evaluation techniques have been used to get the necessary feedback from the subjects such as:-

- In-built evaluation
- Impact evaluation

**In-built evaluation included:**

- Spot evaluation was done after each session to know the subjects’ interest on the topic, knowledge acquisition, clarity and utility of the information provided the method of presentation and if any additional input required.

- Periodic evaluation was conducted at the beginning of ensuing session to study the extent of adoption/practice of information provided during the previous class.

This offered an opportunity for the researcher to have a close watch on the behavioural modifications, if there was any problem in the adoption of modified
practices and also to extent timely support for successful changes in the behaviour of the subjects.

**Impact Evaluation**

This was aimed to study the overall impact of the educational intervention on the target population by way of improvement in KAP as reflected in

- Strengthening the existing desirable practices.
- Getting-rid of the erroneous practices.
- Adopting a modified lifestyle and behaviour to deal with the problems of diabetes.
- Acquiring skill in diabetic self-care and effective glycemic control.

So the impact evaluation mainly dealt with

- Assessment of KAP of the subjects
- Food frequency and food consumption pattern
- Physical activity pattern
- Glycemic control

**Assessment of KAP of the subjects**

Careful designing of measuring instrument to ensure accurate monitoring of an educational programme is highly essential. A test instrument was designed in the present study for assessment of KAP before and after intervention. The instrument consisted of three sections to assess the knowledge, attitude and practice of the subject with the help of a set of questions based on the major concepts dealt with in the package.

For assessing the knowledge regarding diabetic care and management, a set of 40 true or false questions were framed with one point for each correct response.
Attitude or approach to the problem of diabetes was measured using a three point equidistant agreement scale (with scores as 2, 1, 0), a popular format frequently used in the construction of attitude questionnaires. There were 20 questions in this section.

Similarly another set of 25 questions were framed, for studying the self-care and management practices of diabetes by the subjects with a three point scale.

The test instrument was screened by the same panel of experts who had reviewed the learning package, for accuracy, clarity and content validity of the test items. Necessary modifications were done accordingly and was subjected to a validity testing by a pilot study on a comparable group of 20 diabetic patients of the outpatient department of the hospitals, though they were not selected for the intervention study.

For the reliability testing of the knowledge, attitude and practice questions ‘test-retest method’ was used. Finally the instrument was finalised with 40 questions in knowledge, 14 questions in attitude and 25 in practice. The copy of the test instrument is given in Appendix-VI.

The KAP of the subjects were assessed by administering the test instrument prior to and 10 days after the completion of the educational programme, on both control (n=35) and experimental (n=33) groups.

**Food frequency and consumption pattern**

To ascertain the changes if any on the food behaviour of the target population, the two commonly used techniques of diet survey have been used.

- Food frequency questionnaire
- 24 hour dietary recall
Chapter 3

**Food frequency questionnaire**

Food Frequency (FFQ) is widely accepted as the most suitable assessment tool in large epidemiological studies which associate diet with chronic diseases, because they provide dietary information over a long period of time without altering usual food habits and are relatively inexpensive when self-administered (Willett, 1998). This method, with a single measurement, provides a convenient assessment of the habitual dietary intake of an individual. It is accepted that FFQ allows a reasonably accurate ranking of individuals. However, the ability of FFQ to quantify the absolute intake of food and specific nutrients is limited (Ishihara et al., 2009; Sullivan et al., 2008). Subjects are required to indicate how frequently they eat the specified food in terms of servings per day, week or month.

A food frequency questionnaire including the list of food commonly consumed by the people in Kerala was developed (Appendix-VII) and administered on the target population selected for educational programme including both experimental (n=33) and control group (n=35) before and 10 days after the education intervention. Each subject was asked to report the usual frequency of consumption of food and the usual portion size consumed during the previous two weeks. The frequency of consumption was measured on a seven point scale (never/once in a month/twice per month/once in a week/two to three times per week/four to six times per week and daily).

**24-hour dietary recall**

According to Garrow (2000) in diet recall the respondent is asked to recall the actual food and drink consumed on specified days, usually the immediate past 24 hours. In this method, an interviewer asks the subject to recall their food intake for the previous day, over a 24-hour period. An advantage of this method is that the interview is short (approximately 20 minutes). It relies on short term rather than long term memory, and is simple to perform with minimal subject burden.
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The 24-hour recall was done on the experimental \((n=33)\) group before and after the implementation of education programme. The subjects were asked to give complete details on the food they ate and drank except plain drinking water. The researcher recorded it at a face-to-face interview, in the 24-hour dietary recall performa (Appendix–VII), in the presence of a qualified dietician. The food intake was assessed in terms of simple household measures. Food models or photographs were also used to arrive at the portion size.

The mean food and nutrient intake of the subjects and percentage adequacy of the diet were calculated and compared with RDA, computed for diabetic subjects using the guidelines suggested by Raghuram \textit{et al.} (2000). Copy of the RDA of diabetic patient is given in Appendix-VIII.

3.4. Data analysis

The data collected was processed using the Statistical Package for the Social Sciences (SPSS) for Windows version 17.0. The results were presented using frequency, percentage, descriptive statistics like mean and standard deviation. Paired \(t\)-test was used to compare the mean pre-education and post-education scores. Other statistical tools like Independent \(t\)-test, Analysis of variance (ANOVA), correlations and logistic regression methods were also used for data analysis. For comparing the difference in practices of dietary, medical monitoring and other management proportions \(z\)-test were used.

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