CHAPTER THREE:

SUBJECTS AND METHODS
3.1. Setting

The study was conducted at the Diabetic Center, Sana’a, capital of Yemen. The Republic of Yemen is located at the southern part of the Arabian Peninsula, with a total area of 555,000 squares kilometers. Population estimate for 1994 of total resident population of the country is approximately 14 million. The Diabetic Centre is under the Ministry of Health and provides medical care and individual counseling about diabetes. There is no group diabetes education facility at the Centre.

3.2. Study design

A total of 200 adult diabetic patients were recruited in the study as shown in Figure 1. Patients were contacted by telephone or during their OPD attendance at the Diabetes Centre. Of the 200 patients, 182 met the eligibility criteria described below, of which only 177 agreed to join the study. Of these, 150 patients completed all baseline measures. Subjects were randomly assigned to intervention group (who received diabetes education) and control group (who did not receive diabetes education). Pre-intervention base-line measures (i.e. fasting blood glucose, 2-hours post-prandial blood glucose, weight, height measures, demographic characteristics and diabetes history data and data on diabetes knowledge and its management) was completed for all subjects both intervention and control groups). Diabetes education was given to the 75 subjects in the
intervention group. Post-intervention data on diabetes knowledge and its management, fasting and post-prandial blood glucose, weight and height measures were determined for both intervention and control groups. Pre and post intervention changes if any were determined using appropriate statistical analysis as described below. Informed consent was obtained from all subjects before the study was initiated.

Figure 1. Flow chart to show recruitment of patients for the study

200 patients with diabetes contacted from outpatient diabetic clinic list during follow-up visit.

182 patients met all eligibility requirements.

18 patients did not meet eligibility requirements.

177 patients agreed to join study, 89 patients were invited to intervention group took part in diabetes education and 88 patients were invited to control group, did not receive diabetes education.

5 patients refused to join study

150 patients completed all baseline measures and were included in study analysis, 75 intervention group and 75 control group.

27 patients did not complete all measures and were excluded from the study
3.3. Subjects and eligibility criteria

The eligibility criteria for inclusion in the study was as follows:

- Adult diabetic patients greater than 40 years old who attended outpatient diabetic department in Diabetic Center, Sana’a, Yemen Republic
- Male and female patients
- Fully oriented and alert
- Able to speak Arabic language
- Without neurological deficits or history of psychotic disorder
- Willing to participate in this study

**Ethical Consideration**

- Clients were assured that their responses would not influence their care
- Purpose and benefits of the study were explained to the patients
- The patients were assured of confidentiality and they were asked to sign a consent form, which describe the study and indicated that the subjects could withdraw from the study at any time.

**Pilot study**

A pilot study was conducted before the research was undertaken in order to determine whether the proposed study was feasible. A total of 20 adult diabetic patients greater than 40 years old took part in the pilot study using structured questionnaire at the Diabetic Centre, where the main study was
conducted. Necessary alterations were made to the questionnaire following the pilot study.

3.4. Data collection instrument and techniques

1. Knowledge about diabetes and its management:

A structured questionnaire (Appendix IA) was administered in Arabic language in a face-to-face interview. The interviews took place in an office within the outpatient clinic, in order to provide a quiet and relaxed environment. Each interview started with a discussion of study benefits and included signing a consent form and lasted about 15-20 minutes.

The questionnaire was composed of two modules.

1. The first module which included: demographic characteristics and diabetes history of study sample, i.e.

   - Demographic details (name, age, sex, marital status, level of education, occupation and family income per month).

   - Diabetes history (type of diabetes, duration of diabetes, visit frequency, types of treatment and family history).

2. The second module included questions which assessed knowledge about diabetes and its management, i.e.

   - Nature of diabetes and its complications (definition, causes, signs and symptoms and acute and long-term complications)
• Medications (oral hypoglycemic agents and insulin)
• Diet
• Exercise
• Self-monitoring (blood glucose, urine test for ketones)
• Self-care (skin-care, foot-care, eye-care and teeth-care)

2. Body Mass Index (BMI):
The body weight and height were measured with light clothes and without shoes. Body mass index (BMI) was calculated by dividing body weight (in kg) by power of height squared (m²).

3. Blood glucose (fasting and 2-hours post-prandial):
Fasting blood glucose levels and 2-hours post-prandial blood glucose measurements were conducted for all subjects twice, once at the beginning of the study and once after 6 months at the end of the study. Blood samples from the subjects were collected and analyzed at the pathology laboratory of the Diabetes Centre. The value of blood glucose was determined using Bayer Technical RA 100 Autoanalyzer. These were supplied by Technical Chemical Co. SA (Bayer) B. 7501 Tournai, Belgium.

4. Diabetes Self-Management Education:
The seventy-five patients in the intervention group were assigned to ten groups. Each group was given diabetes education once every two weeks
for six months. Appendix II gives the contents of the diabetes education program and examples of posters, pamphlets and other educational materials used in the education. All topics were given as 1 to 2 hours theoretical and/or practice sessions to the groups. Education sessions were carried out by the researcher who has B Sc. Nursing and M Sc. in General Nursing Education (Community Health Nursing Instructor, Sana'a University, College of Medicine and Health Sciences). The diabetes education program was structured in the following measures (Appendix II):

1. Nature of diabetes and its complications

   • Definition of diabetes mellitus
   • Types of diabetes mellitus
   • Causes of diabetes mellitus
   • Signs and symptoms of diabetes
   • Acute complications
     1. Hypoglycemia (causes, recognition, treatment and prevention)
     2. Hyperglycemia (causes, recognition, treatment and prevention)
   • Long-term complications (Heart, kidney, eyes and feet)

2. Medications (oral hypoglycemic agents and insulin therapy)

3. Exercise

4. Diet planning
5. Self-monitoring (blood glucose and urine test)
6. Self-care (skin-care, foot-care, eye-care and teeth-care)
7. Sick day role

3.5. Data processing and analysis

1. Demographic characteristics and diabetes history

Data was analyzed using Microsoft Excel and Statistical Package for Social Sciences (SPSS) Version 9.0. Data from the sample regarding demographic characteristics and diabetes history were measured using descriptive statistics (frequencies, percents, means and standard deviations) and Chi-Square test ($\chi^2$).

2. Knowledge about diabetes and its management

Diabetes knowledge was evaluated through analysis of 35 questions and a score of one was awarded for each correct answer (Appendix IB). Knowledge about diabetes and its management was categorized as good when scores ranged from 55 to 100, moderate when scores ranged from 45 to 54 and poor when scores were less than 45 points.

3. Calculation of (BMI)

Obesity was defined as BMI>25 kg/m$^2$ in males and >27 kg/m$^2$ in females. Normal body weight was considered when BMI value ranged from 19 to 25
kg/m² in males and from 19 to 27 kg/m² in females. Subjects with BMI value less than 19 kg/m² were considered under weight¹⁰⁴,¹³⁹,²³⁴ (Table-11).

4. Blood glucose levels

Categorization of blood glucose levels as good, moderate and poor were based on Eurodiab recommendations⁵⁶. Subjects were considered to have good control if fasting blood glucose was 4.4–6.1 mmol/L and 2-hours post-prandial blood glucose was 5.5-8.0 mmol/L. Subjects were categorized as moderate when the fasting blood glucose was 6.2-7.8 mmol/L and 2-hours post-prandial blood glucose 8.1-10.0 mmol/L. Poor control was when the fasting blood glucose was >7.8 mmol/L and 2-hours post-prandial blood glucose was >10.0 mmol/L (Table-11).

- Measurement of impact of intervention:

Pre and post diabetes education knowledge, blood glucose (fasting and 2-hours post-prandial) levels and body mass index (BMI) was compared between groups using Chi-Square test ($\chi^2$) and Z-test.
CHAPTER FOUR:

RESULTS
Table 11. Summary of measures and their categorizations

<table>
<thead>
<tr>
<th>1-Knowledge</th>
<th>Good</th>
<th>Moderate</th>
<th>Poor</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>55-100</td>
<td>45-54</td>
<td>&lt;45</td>
<td>This study</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2-Blood glucose</th>
<th>Good</th>
<th>Moderate</th>
<th>Poor</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting blood glucose (mmol/L)</td>
<td>4.4–6.1</td>
<td>6.2–7.8</td>
<td>&gt;7.8</td>
<td>Eurodiab^56</td>
</tr>
<tr>
<td>2-hours-post-prandial (mmol/L)</td>
<td>5.5–8.00</td>
<td>8.1–10</td>
<td>&gt;10</td>
<td>Eurodiab^56</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3-Body mass index</th>
<th>Underweight</th>
<th>Normal weight</th>
<th>Obesity</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;19 kg/m^2</td>
<td>Male:19–25 kg/m^2 Female:19–27 kg/m^2</td>
<td>Male:&gt;25 kg/m^2 Female:&gt;27 kg/m^2</td>
<td>Garrow^104, Keen^139, and Tomkins^234</td>
</tr>
</tbody>
</table>