

CHAPTER 3

RESEARCH METHODOLOGY

The purpose of this chapter is to discuss the research methodology and to outline the specific methods and procedures that was used to carry out the study.

Study Design

A quasi-experimental study with two group pretest-posttest design was used in this study. It aimed to examine the effect of the supportive-developmental nursing program on self-care practices among diabetes patients.

Population and Setting

The target population in this study was new Type 2 diabetes patients who had been diagnosed having the disease not more than 3 months attending diabetes clinic at the outpatient clinic, University Hospital Science Malaysia, Kubang Kerian, Kelantan, Malaysia. The clinic serves for population of diabetes referred from other district hospitals. It operates from 8.10 a.m. to 2.00 p.m. on Sunday, Monday, Tuesday, and Wednesday. The average number of diabetes patients attending the clinic is 40 patients per day and a total of 160 patients per month, recent statistic in 2005 from diabetes clinic shows that the numbers of Type 2 diabetes increased by month. In January there were 36 new cases of Type 2 diabetes and increased by 11 patients in February and the total numbers increased again to 54 in March (Statistic Report of Outpatient Clinic of University Hospital Science Malaysia, July 2004).

Sample

Sample size

Power analysis was used to estimate the number of the subjects in this study. Power analysis is useful to ascertain the significance of the study findings. There are three components to estimate the required sample size by using alpha (" α ", level of significance), 1-beta (" $1-\beta$ ", the power of the test), and gamma (" γ ", population effect or effect size) (Polit & Hungler, 1999).

Many previous studies (De Sonnaville et al., 1997; DeSouza & Nairy, 2003; Knight et al., 2005; Masawang, 2001; Puangkun, 2001) had used quasi-experimental study with pre and post-test to study the effects on self-care behavior of diabetic patients, by comparing food practices, taking care of feet, exercise behavior and medication taking. It was found that patient education had an effect on self-care behavior by improving food practices, taking care of feet, complication prevention, and medicine taking with statistically significance difference. A meta analysis studied by Likitracharoen (2000) concluded that the weighted mean effect size for self-care ability ranged from 1.37-1.93 and the average effect size was 1.65. Instead of measuring all four variables that are: 1) self-care behavior or skill performance, 2) self-care deficit, 3) self-efficacy, and 4) adaptation, the researcher only measure the first variable. Due to differences, in measuring the depending variable, the researcher used the medium effect size of 0.36, alpha level of .05 and power of .80. Therefore, an adequate sample size of this study was 30 patients in each groups.

Sampling methods

Purposive sampling method was used to determine qualified subjects in this study. Patients' health record from outpatient clinic at University Hospital Science Malaysia was reviewed to identify the potential subjects. The following inclusion criteria were used to recruit for control and experimental group in this study.

1. Being diagnosed of Type 2 diabetes mellitus not more than three months.
2. Voluntarily consent to participate in the study.
3. Never been admitted in hospital because of diabetes.
4. Able to communicate in Malaysian language.

Instrumentation

Four forms of instruments were used for data collection. They were: (1) Demographic and Health Information Form, (2) Diabetes Self-Care Practice Questionnaire, (3) Manual Handbook, and (4) Supportive-developmental nursing care plan. The Diabetes Self-Care Practice Questionnaire was tested for its content validity and reliability, while the Supportive-developmental nursing care plan was evaluated for content validity.

Demographic and health information form

The instrument was designed by the researcher to assess the demographic data and health status of patients, such as age, gender, religion, level of education, marital status, occupation, income, duration of disease, and current prescribed medications (Appendix B).

Diabetes self-care practice questionnaire

The questionnaire developed for this study was based on Dougchan's (2004) self-care practice questionnaires which used to measure nurses' capabilities in promoting self-care practice of diabetes patients. The original version was translated from Thai to English by a bilingual Thai-English expert. The three steps of self-care practice for diabetes patients reflected in the questionnaire were adopted. They were: 1) seeking knowledge, 2) making decision and judgment, and 3) operating practice. Each step was composed of items reflecting the effectiveness of self-care practices for the five actions to be performed by the Type 2 diabetes, i. e., 1) dietary control, 2) exercise, 3) medication taking, 4) stress management, and 5) personal hygiene.

The questions that measured three levels of ability to care for self of Type 2 diabetes patients were: (1) seeking of relevant knowledge and information, (2) making decision and judgement, and (3) producing or operating activities. Each level covered the five aspects of self-care demands of the Type 2 diabetes patients. The numbers of questions in each level were as the followings.

1. Seeking of relevant knowledge and information: 15 questions (No. 1, 2, 3, 10, 11, 12, 19, 20, 21, 27, 28, 29, 36, 37, 38).

2. Making decision and judgment: 15 questions (No. 4, 5, 6, 13, 14, 15, 22, 23, 24, 30, 31, 32, 39, 40, 41).

3. Producing or operating activities: 14 questions (No. 7, 8, 9, 16, 17, 18, 25, 26, 33, 34, 35, 42, 43, 44).

The questionnaire was a rating scale ranging from 1 to 6. The higher the score, the higher level of self-care practice. The total scores, ranged from 44 to 264. The English version of the Diabetes self-care practice questionnaire was translated to Bahasa Malaysia by a bilingual Malay-English expert.

Validity. The content validity of the Diabetes Self-Care Practice Questionnaire was evaluated by five experts. One expert in the area of diabetes was from Medical Faculty of

University Science Malaysia. Two theory experts were lecturers from Nursing, Prince of Songkla University, Thailand. The other was experienced in provision of care for diabetes patients from University Hospital Science Malaysia. These experts were asked to evaluate each item. Then, the researcher modified the items based on the experts' recommendations.

Reliability. The Diabetes Self-Care Practice Questionnaire was administered to ten patients with Type 2 diabetes for testing its reliability. The internal consistency was evaluated by using Cronbach's alpha coefficients. The coefficient alpha of self-care practice was .97. The alphas of each dimension in self-care practice questionnaire were: 1) dietary control was .97, 2) exercise was .98, 3) medication taking was .97, 4) stress management was .97, and 5) personal hygiene was .96. The coefficient reliability of .70 was considered satisfactory and acceptable for a new developed tool according to Polit and Hungler (1999). Thus, the Diabetes Self-Care Questionnaire was at appropriate reliable tool to measure the self-care practice of Type 2 diabetes.

Manual handbook

The education guideline for diabetes patient was developed by Epidemiology Unit of Health Department Kelantan in year 2004. The content validity was approved by the experts in the Ministry of Health Kelantan. The education guideline was used in the entire health centre in Kelantan for teaching purposes and self reading for diabetes patients at home. The content consists of definition of diabetes, its clinical effects, and severity of its complications, including the patients' self-care management on dietary control, exercise, medication taking, stress management, and personal hygiene. The content was divided into seven modules as following:

Module 1: Introduction to diabetes

Module 2: Guidelines for diabetic diet

Module3: Diabetes and exercise

Module4: Diabetes and medications

Module 5: Management of diabetes during special occasion

Module 6: Monitoring of diabetes

Module 7: Diabetes and complications

Supportive-developmental nursing care plan

The nursing care plan was developed by the researcher. It consists of plan for teaching, guiding, support and providing environment to promote self-care practice for the diabetes

patients. The teaching content was based on the education guideline for diabetes patients designed for group and individual teaching. (Appendix D).

The content validity of Supportive-Developmental Nursing Plan was evaluated by four experts. Two experts in the area of diabetes were from Nursing Faculty in Prince of Songkla University, Thailand. Two other experts, one was a diabetologist and the other was nursing lecturer with experience in diabetes care, were from University Science Malaysia, Kelantan.

Intervention

The Type 2 diabetes patients were approached on the first day of their visits or the appointments at the outpatient clinic in order to seek their consent to participate in the study. The researcher explained to each subject regarding objectives, subject's right, and outcomes of the study. When the subject agreed to participate in this study, consent form was given. Then, the Demographic and Health Information Forms, and Diabetes Self-Care Practices Questionnaire were administered for both control and experimental groups. The questionnaires were reviewed after completion. This process was repeated every week for both groups until the number of subjects for each group reached the desired sample size.

The eligible subjects in the study were divided into two groups: control and experimental groups. There were 30 subjects in each group. The researcher started with the control group, followed by the experimental group. The control group received only the usual care by the doctors and nurses at the clinic. The usual care consisted of 1) advising the patients on dietary control, exercise, medication, stress management, and personal hygiene, and 2) encouraging the patients to follow treatment regimen by making routine appointment at the outpatient clinic. The experimental group received usual care and supportive-developmental nursing program.

The control group received usual care from doctors and nurses at the outpatient clinic, while the experimental group received supportive-developmental nursing program by the researcher. The supportive-developmental nursing program consists of five activities: 1) teaching: introduction to diabetes mellitus, guidelines for diabetic diet, diabetes and exercises, diabetes and medication, management of diabetes during special occasion, monitoring of diabetes mellitus, and diabetes and complication, 2) guiding, 3) supporting, and 4) providing environment for self-care development.

The experimental group

The subjects for the experimental group were recruited after completion of the control group. An average of 7–10 subjects was recruited for each teaching session. The teaching session was held for three weeks. The group size for each teaching session and the number of teaching session were suggested by Health Care Finance Administration of Minneapolis in a study conducted by Rickheim, Weaver, Jill, and Kendel (2002) on assessment of group versus individual diabetes education. After completion of teaching activities, data for post intervention were collected.

Nursing intervention included teaching, guiding, supporting, providing environment, and building relationship for self-care development. The purpose of this nursing intervention was to enhance the diabetes capability to attain their role toward self-care practices. This intervention was conducted as follows:

The first session (1st visit)

1. Teaching. The teaching contents of general knowledge on Type 2 diabetes, causes of Type 2 diabetes, risk factors of diabetes, symptoms of Type 2 diabetes, how to monitor Type 2 diabetes, and its complications. The teaching session was held at the diabetes clinic which lasted for thirty minutes. The second module of the teaching was on guidelines for diabetic diet. It emphasized on three categories of dieting, that important to person with diabetes. The category of diet included food that should be avoided, food that was allowed, and food portion. The aims were to enable the patients to developed and perceived benefits of promoting self-care practices.

2. Guiding and supporting. In the second half of the session which is the last thirty minutes, the diabetes patients were asked about their needs related to self-care practices. The conversation was held at the diabetes clinic and it lasted for thirty minutes. The patients were asked about their health problem and feeling than it was discussed with them how to identified the problem and its causes. The diabetes patient were offered alternative and what their choice to do was accepted by the researcher while the patients were assisted in developing self-care skill, they were allowed to asked any question. The diabetes patients were offered nursing assistances by the researcher in polite, calm and respectful manner. The diabetes patients were encouraged to perform into self-care practices and were praised when they tried to do so. The guideline for diabetes patients of the two modules was given to them for reviewing and practicing at home. The

guideline was produced by Epidemiology Unit-NCD, Health Department of Kelantan, Ministry of Health (2004).

3. Providing environment for self-care development. A comfort and conducive room was prepared at the diabetes clinic by the researcher. This was encouraged patients to participate. It lasted for one hour. Diabetes patient who met was asked about their health problem. The diabetes patients were encouraged to express their feelings, concerns, and worries. Besides that they were encouraged to ask any questions.

4. Prior to second session (2nd visit), subjects had received an appointment date for health education.

5. Patients continued to receive usual care at the out-patient clinic.

The second session (2nd visit)

1. Teaching. On the second meeting in the second week the patients received health education, based on the third module and the fourth module. The content emphasized on exercise and medication management. The teaching session was provided on the second week at the diabetes clinic and lasted for thirty minutes.

2. Guiding and supporting. Foot exercise was demonstrated by the researcher. The diabetes patients were provided with encouragement by asking them to review the procedure and to demonstrate the total exercise. The conversation and demonstration were held at the diabetes clinic and lasted for thirty minutes. Then the patients received printed material of the two modules from the handbook at the end of the session for revision at home. The handbook was produced by Epidemiology Unit of Kelantan, Ministry of Health (2004).

3. Providing the environment. A rapport was established by sharing information about the previous modules and the problems of the patients. They exchanged experiences, share their opinions on performing self-care at home, and solve their problems. A comfortable place and conducive room was prepared at the diabetes clinic for the diabetes learning and participation in the teaching session and lasted for one hour. The room should be soundproof so that the noise from outside could not evade it. A return demonstration according to the manual handbook of the activities was provided, if the patients needed it.

4. Prior to the third session (3rd visit), subjects had received an appointment date for the final health education.

The last session (3rd visit)

1. Teaching: The diabetes patients received education, based on the fifth, six, and seven modules. The content of the modules emphasized on special occasion such as fasting, traveling, social interaction, mild sickness, pregnancy, monitoring of glucose level, and complications of diabetes such as hypoglycemia, hyperglycemia, and ketoacidosis. The teaching session was provided on the third at the diabetes clinic and lasted for one hour.

2. Guiding and supporting. The diabetes patients were asked to identify problem and their causes. The conversation was held at the diabetes clinic and lasted for thirty minutes. The diabetes patients were offered alternative choices of solution and it was discussed and the researcher accepted their choices while the patients were assisted in developing the skill, the researcher will give praise, respect and approach everything in a calm, and soft manner.

3. Providing environment for self-care development: The relationship was continuing maintained. A comfortable and conducive room which provided at the diabetes clinic. The teaching session lasted for one hour. The diabetes patients received printed material for the fifth, sixth and seventh module for revision at home.

The control group

The usual care was given to subjects in the control group by the doctors and nurses at the diabetes clinic. The usual care that was provided to diabetes patients were dietary control, exercises, medication, stress management and routine appointment at the out-patient clinic. The usual care given by doctors took 10-15 minutes. Sometimes the usual care was provided by nurses in a room in the diabetes clinic. The media used included flip chart and pamphlet. Then, subjects were acknowledged for their participation.

Ethical Consideration

This study was conducted with the intention of protecting the human rights of all subjects through the following processes.

1. Permission from Institutional Review Board of Nursing Faculty, Prince of Songkla University was obtained.

2. Permission for data collection in this study was obtained from Director of University Hospital Science Malaysia, Kubang Kerian, Kelantan, Malaysia.

3. Subjects who were willing to participate in this study were asked to sign a consent form. In addition, they were told that they can withdraw from participating at any time.

4. The subjects who participate were assured that anonymity and confidentiality of subjects were protected at all times. The data were kept confidentially by the researcher. The researcher were protected the subjects' privacy through anonymity by using coding system to identify the subjects.

Data Collection

Data collection was conducted after the approval from the Graduate School and Faculty of Nursing, Prince of Songkla University. The data collection procedures were divided into two phases: 1) preparation phase, and 2) implementing phase.

1. Preparation phase

(1) Asking permission to collect data by submitting a letter from Faculty of Nursing Prince of Songkla University to inform the Director of University Hospital Science Malaysia, Kubang Kerian, Kelantan, about objectives of the study and procedures of data collection.

(2) Asking the head nurse of Outpatient Clinic at University Hospital Science Malaysia to find one nurse who were willing to be research assistants in this research.

(3) Research assistants were informed, by the researcher, about her responsibility in assisting the researcher collected questionnaires returned from the subjects.

(4) Preparing packages of questionnaires including a covering letter and two sets of questionnaires for the subjects (Demographic and Health Information Form, and Diabetes Self-Care Practice Questionnaire).

2. Implementing phase

(1) Sixty subjects of Type 2 diabetes from the diabetes clinic of University Science Malaysia were included in this study.

(2) The package of instruments used for data collection was consisted of the Demographic and Health Information Form and Diabetes Self-Care Practice Questionnaire, couple with a covered letter informing each subject about protection of human rights, purposes

and procedures of the study, and consent form. Both instruments were administered at pre-test for experimental and control groups. However, only Diabetes Self-Care Practice Questionnaire was given at post-test. The time to complete the two questionnaires for each subject was 15-20 minutes.

Control group

The researcher explained the purpose of the study in order to seek their consent and participation in this study. Each subject was explained regarding the objectives, subject's right, and outcomes of the study. If the subject agrees to participate in the study, they were asked to sign a consent form. After having permission from the subjects, the researcher asked the subjects to complete the Demographic and Health Information Form, and the Diabetes Self-Care Practice Questionnaire. After the subjects completed the Diabetes Self-Care Practice Questionnaire and appointment date were given for the next visit, which was on the fourth week. The post-test Diabetes Self-Care Practice questionnaires were given to the subjects and collected by research assistant.

Experimental group

The subjects were asked to complete the Demographic and Health Information Form and the Diabetes Self-Care Practice Questionnaire before the intervention of supportive-developmental nursing program. After completing the three sessions of intervention, research assistant distributed Diabetes Self-Care Practice Questionnaire by the following week. After completing post-test Diabetes Self-Care Practice questionnaires, the researcher acknowledged them for their voluntarily participation.

Data Analysis

The collected data were processed using SPSS version 11 (Statistical Package for Social Sciences). The data analysis was conducted using the following statistics.

1. The demographics and health information data of subjects were analyzed and described in frequency, percentage, range, mean (\bar{X}), and standard deviation (SD).

2. Self-care practices between experimental group and control group were analyzed by using analysis of covariance (ANCOVA) to determine the mean total scores of the self-care practices and mean of subtotal score of self-care practices at post-test intervention. Pre-test score of self-care practices was used as the covariate.

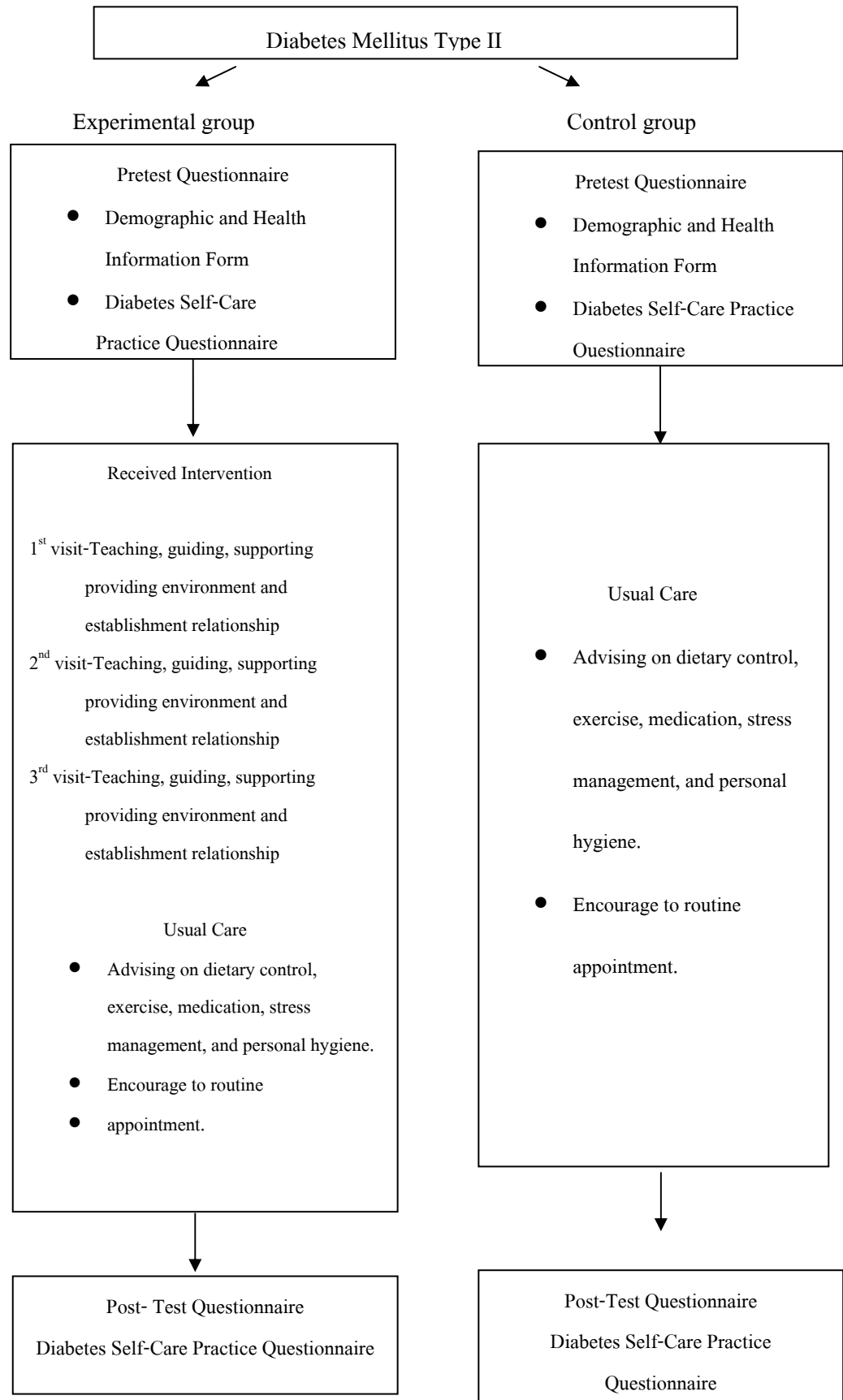


Figure 2: Intervention of the study.