CHAPTER 3

METHODOLOGY

This Randomized Control Trial (RCT) was designed to determine the effects of a Diabetes Self-Management program on knowledge of diabetes, glycemic control, cardiovascular (CVD) risk, and quality of life (QOL) for Thai people with type 2 diabetes in two rural communities. It examined the difference between the effects on people who participated in a Diabetes Self-Management program and those who received the usual care.

Variables: The independent variable was a diabetes self-management program for people with diabetes. Dependent variables included knowledge of diabetes, glycemic control, CVD risk, and QOL.

Population and Sample

This Randomized Controlled Trial was designed to determine the effects of a Diabetes Self-Management program on the knowledge of diabetes, glycemic control, CVD risk, and QOL for Thai people with type 2 diabetes who lived in Chanthaburi province.

The target populations for this study consisted of adults with type 2 diabetes who lived in Lhamsing district, Thamai district, and the surrounding area in Chanthaburi province, and came for follow up care at the diabetic clinic at either two community

hospitals or primary care settings. The sample for this study consisted of known adult cases with type 2 diabetes who used an out-patient setting for follow- up care.

Inclusion criteria were people with type 2 diabetes who: 1) were ≥ 35 years old and have been diagnosed with type 2 diabetes for at least six months; 2) had a fasting plasma glucose of more than 140 mg% for at least two follow up visits; 3) were able to read and write in Thai; and 4) were willing to have the researcher visit their home.

Exclusion criteria: were people with type 2 diabetes who: 1) had severe complications, which made them unable to participate in this program; and 2) were being treated by using insulin therapy.

Discontinuation criteria: were people with type 2 diabetes who: 1) had severe complication during the program; 2) had to be treated with insulin; 3) did not complete participation in intervention sessions. Patients in each research setting (4 settings) were randomly assigned into a diabetes self-management intervention group and a usual care group.

Sample Size

An estimate of the sample size in this study was calculated by using a sample size determinant formula for repeated measurement analysis (Viwatwongkasem, 1994) with a level of significance of α =.05 (probability of type 1 error) and a power of .90 (1 - probability of type 2 error). The sample size formula is:

$$n = \frac{(Z_\alpha + Z_\beta)^2 \times 2\sigma^2}{\delta^2}$$

n = estimated sample size

Z_α = 1.645 for significant level at .05 (95% confidence desired)

Z_β = 1.282 (10% beta error, 90% power desired)

δ = $\mu_1 - \mu_2$ (mean difference between experimental group and control group

σ = standard deviation

Likitracharoen (2000) conducted a meta-analysis of educative-supportive intervention research for diabetic patients in Thailand, findings showed that the weight mean effect sizes of glycosylated hemoglobin (HbA_{1c}) was 0.56.

Effect size was calculated using the following formula suggested by Polit and Beck (2004: 497). In a two-group situation, the formula for the effect size is:

$\gamma = \frac{\mu 1 - \mu 2}{\sigma}$ That is, assuming the sample size for estimated effect is:

$$n = \frac{(1.645 + 1.282)^2 X 2}{(0.56)^2} \; ; \; n = 55$$

The previous similar studies in Thailand reported the attrition rate of intervention was around 8-10%; therefore, the sample size should be estimated for 10% of an attrition rate.

$$n = \frac{55}{90} X 100 = 61$$

The sample needed for this study would be approximately 61 people per group. Therefore, the total number of subjects needed in this new study is 122 people. However, in this study the researcher planned to prevent losing subjects from dropout rate by adding 30% for estimation sample size because the intervention in this study was conducted in a longer period of time (6 months) compared to previous studied (approximately 4 months). Therefore, the number of subjects needed in this new study is 156 people.

Research Setting

This experimental study was conducted at two community hospitals, two primary care units, and patients' homes in Lhamsing district; Thamai district, and the surrounding area in Chanthaburi province. The first hospital is a community hospital with 30 in-patient beds, which provides services to people in 16 villages in Lhamsing district and the near area. This hospital is located 20 kilometers from Lhamsing city and serves a population of 30,000 people. There are three general physicians and other health care professionals with approximately 40 people working in the hospital. The second hospital is a community hospital with ten in-patient beds, 2 physicians and 61 other health professionals which provides services to 15, 000 people residing in seven villages and the surrounding area. This hospital is located 22 kilometers from the city. Generally, community hospital provided curative care, health promotion, and disease prevention. The services for people with diabetes are provided at the diabetic clinic, Out - Patient Department (OPD). At the first hospital, the clinic is opened only on Thursday from 08.00 to 12.00 a.m., while at the second hospital, the diabetic clinic service is provided on Thursday and Friday from 08.00 to 12.00 a.m.

The study sample was also recruited from two primary care units. The first unit is located in a community health post, providing care to 3,592 people in six villages, Lhamsing district. The health staff at this primary care unit is composed of a health worker, a registered nurse and two community health workers. The second primary care unit is located at a health center, serving a population 9,264 people in 16 villages, Lhamsing district. Services provided at these primary care units include health promotion, disease prevention and simple curative care and home health care. The primary care units' staffs run health programs using the standard procedures established by the Ministry of Public Health, under the technical supervision and support of the community hospital. The services of diabetic clinic at both primary units were provided by the health care team from the community hospital consisting of a physician, registered nurses, and a pharmacist. The first primary care unit provides services for people with diabetes once a week on Tuesday from 06.00 to 12.00 a.m. The second primary unit provides service on Wednesday from 07.30 to 12.00 a.m. The routine clinical service routines or the usual care in diabetic clinics and community hospitals are similar in the following ways:

People with diabetes come to diabetic clinic around 06.00 - 07.30 a.m. and they have a blood pressure check. Then, their weight is measured, and blood test for fasting plasma glucose or an additional blood sample is taken to test kidney function and/or cholesterol. They may also need to provide a sample of urine for measurement of protein before seeing the physician. During waiting to see the physician (07.30 - 09.30 a.m.), health education is provided by registered nurses who work at the diabetic clinic or by other health care provider such as pharmacist. Common health education is mostly provided for all people with diabetes who come for follow-up

visits at the out-patient department by institutional guideline without a structured program. The services provided by physicians usually start at 09.30-10.00 a.m. People with diabetes see the physician for approximately 3-10 minutes, during which time they are examined, and talked with about their conditions, treatments, and given advice. After receiving treatment, people with diabetes come to see the registered nurses at the front-desk to make the next clinic appointment. Appointments are booked at approximately 3-5 minute intervals so they would be allocated about 3-5 minutes for individual consultation. Then, they obtain their medications and receive advice regarding proper medication taking from a pharmacist.

Instrumentations

1) The Instruments for Research Procedure: (see in Appendix A)

1.1 *The Nursing Manual for Promoting Diabetes Self-Management of People with Diabetes.* This instrument was developed by the researcher. The sessions were highly interactive, with emphasis on efficacy-enhancing strategies, frequent group problem-solving sessions and individual problem-solving and reinforcement sessions. Diabetes education and strategies for promoting self-efficacy in diabetes self-management were provided.

These techniques included: 1) *formulating action plans*: the researcher demonstrated goal techniques through action plans, which taught patients how to break long term goals into incremental steps. At the end of each class, participants devised their weekly personal action plans. The plans were required to be behavior specific. Patients reported on the success or barriers of their action plans at the beginning

of the next class; 2) *skill mastery*: participants were asked to try the new behaviors in each group discussion. Each session included time for feedback on processes and discussion of problems. Skill mastery techniques included practice in meal planning, exercise/physical activities, signs and symptoms monitoring, medication taking, and meditation techniques were trained; 3) *modeling*: the researcher encouraged successful people who perform appropriate behaviors to be models to other participants by demonstrating desired behaviors; 4) *persuasion*: the researcher encouraged participants to undertake more activities than they have been accomplishing and support them as they began making lifestyle changes. Regular contact throughout the follow-up was promoted; and 5) *physiological and emotional arousal:* re-interpreting symptoms were promoted. Participants were taught about physical and emotional problems. Each problem was discussed. Problem-solving, anticipation of barriers and maintenances of new behaviors were encouraged. Possible causes of problems were identified and self-management was promoted for making adjustments to attain goals.

1.2 The Patient's Personal Manual for Enhancing Glycemic Control and Quality of Life named "Living Well with Diabetes" were developed by the researcher. The contents were composed of: general knowledge about type 2 diabetes; the ability of patients' to participate in diabetes self-management; goal setting; appropriate diabetes self-management behaviors; methods for monitoring progress; and self-evaluation of glycemic control.

2) The Instruments for Data Collection:

2.1 A Demographic Data Sheet was developed by the researcher to collect personal data including age, gender, educational level, marital status, occupation,

income, BMI, duration of illness, height, weight, history of illness, history of smoking, FPG, HbA_{1c}, total cholesterol, HDL, LDL, TG, BP, medication, and complications related with diabetes.

2.2 The SF-36 Thai version 2: the SF-36 was originally developed in English. It was translated into Thai language by Methakanjanasak (2005). The SF 36 is divided into a total of 36 items for measuring physical-psychosocial well being that assesses eight health concepts: 1) limitations in physical activities, 2) limitations in social activities, 3) limitations in usual role activities, 4) bodily pain, 5) general mental health, 6) limitations in usual role activities, 7) vitality, and 8) general health perceptions (Ware & Sherbourne, 1992). In type 2 diabetic patients, Cronbach alpha's ranged from .69 to .95, the scale reliabilities coefficient ranged from .77 to .91 and all scales possessed acceptable levels of reliability coefficient (Anderson et al., 1997). The SF-36 was translated and has been used in Thai cardiac patients. The Cronbach's alpha coefficient exceeded .70, and all inter-item correlation exceeded .40 (Krittayaphong, et al., 2000). The reliability coefficient of the SF-36 version 2 was tested in 10 end stage renal disease patients receiving hemodialysis and the Cronbach's alpha coefficient reported at .86 (Methakanjanasak (2005).

Score of all dimension of QOL ranged from 0 - 100. They were classified into three equal levels, namely low (0 - 33.33), moderate (33.34 - 66.67), and high (66.68 - 100).

2.3 The Diabetic Knowledge Scale: Participants' knowledge of diabetes was measured by Diabetic Knowledge Scale: developed by Arunneatara (2005). It was used to measure diabetic knowledge. The Diabetic Knowledge Scale contains 20 items which were answered in a multiple choice format. It was divided into items

about characteristics of diabetes mellitus, signs and symptoms, dietary controlling, exercise/physical activity, medication taking, foot care, wound care, general self-care, and medical administration.

This scale was initially tested for the content validity and objectivity by a panel of experts including two endocrinologists, two nurse instructors who were experienced in the area of diabetes care, a nurse instructor who was expert in psychology, and a nurse instructor who was expert in behavioral science. The reliability of Diabetic Knowledge Scale was initially tested in 30 diabetic patients. The Kuder-Richardson 20 (KR-20) was .75 (Arunneatara (2005).

Scores of all dimension of knowledge ranged from 0 - 20. They were classified into three equal levels, namely low (0 - 6.67), moderate (6.68 - 13.35), and high (13.36 - 20.00).

2.4 The Biotech Semi-Automate Analyzer was used for measuring fasting plasma glucose (FPG). The normal range of FPG is 70 - 99 mg % , FPG levels 90 - 130 mg% is considered good diabetes control, >130 - 180 mg% is considered fair glycemic control, and > 180 mg% is considered poor glycemic control (ADA, 2003; 2004).

2.5 The Primus Nycocard Analyzer was be used for measuring HbA_{1c}. The normal range of HbA_{1c} is 4 - 6 %. HbA_{1c} levels < 7% is considered good glycemic control, 7 - 8% is considered fair glycemic control, and > 8% is considered poor glycemic control (ADA, 2001; Ryan, Camu, & Tenzler, 2006).

2.6 The Beckman Coulter Syncron CX 7 Delta Chemistry Analyzer was used for measuring serum lipid. Serum lipid is associated with cardiovascular events.

As mentioned by the National Cholesterol Education Program (NCEP) Expert Panel (2001), the classifications of lipid profile are divided as follows:

Total cholesterol < 200 mg/dl is considered desirable, 200 - 239 mg/dl is borderline high, and ≥ 240 mg/dl is considered high total cholesterol.

LDL cholesterol is estimated from measurements of total cholesterol, total glycerides, and HDL cholesterol. LDL cholesterol can be calculated as follows:

LDL cholesterol = total cholesterol – HDL cholesterol – (triglycerides/5)

LDL < 100 mg/dl is considered optimal level, 100 - 129 mg/dl is near optimal or above optimal, 130 - 159 mg/dl is considered as borderline high, 160 - 189 mg/dl is high, and ≥ 190 mg/dl is considered very high.

HDL cholesterol < 40 mg/dl in men, and < 50 mg/dl are considered as low, HDL cholesterol ≥ 60 mg/dl is considerable desirable.

Triglyceride < 150 mg/dl is considered normal, 150 - 199 mg/dl is borderline high, 200 - 499 mg/dl is high, and ≥ 500 mg/dl is considered very high.

Based on the level of coronary heart disease (CHD) risk in the view of the International Task Force for Prevention of Coronary Heart Disease (Assmann, et al., 2005; NCEP, 2001), asymptomatic patients is classified into the three categories in the low or moderate risk (< 10% event risk in 10 years), intermediate risk (10 - 20% 10-year risk) and high risk (> 20% 10-year risk).

2.7 A Sphygmomanometer was be used for measuring blood pressure. Measurements followed the guidelines of the American Heart Association (2004). Systolic blood pressure < 130 mmHg, and diastolic blood pressure < 80 mmHg are recommended as a good blood pressure control (ADA, 2003, 2004).

In terms of the cardiovascular risk, this study is regarded as a CHD risk, as estimated using the formula from the Framingham Heart Study Coronary Heart disease Risk Prediction (Marrugat et al., 2003, p 637) (see Appendix B). Calculations utilized risk factor levels for subject age, HDL cholesterol, total cholesterol, systolic blood pressure, smoking status, diabetes diagnosis, and were based on the assumption that subjects did not have left ventricular hypertrophy (Lemon, 2004; Marrugat et al., 2003).

The Psychometric Testing:

1) The Nursing Manual for Promoting Diabetes Self-Management of People with Diabetes and the Patient's Personal Manual for Enhancing Glycemic Control and Quality of Life (Living Well with Diabetes)

Both manuals were approved by five panel experts. One endocrinologist who is expert in diabetes, three nurse instructors who are expert in diabetes mellitus, and one clinical nurse who is expert and has experience related to diabetes area (see Appendix C). These experts were requested to review the content in the manual to clarify, and to prove its adequacy in terms of construct validity of the manual and appropriateness. Face validity was also used to evaluate the content validity of the patient's personal manual by using three diabetic patients to evaluate the readability and understandability of the participants, and the modified some wording that was ambiguous or unclear.

2) The SF-36 Thai version 2

In this study, the researcher tested the reliability of the SF-36 Thai version 2 with 20 Thai people with type 2 diabetes at a community hospital, where has similar diabetic services to the research setting in Chanthaburi. The Cronbach's alpha coefficient was used to analyze the data. Results showed that the Cronbach's alpha coefficient = .75. The final test in 147 diabetic patients reported the Cronbach's alpha coefficient at .92.

3) The Diabetic Knowledge Scale

The Diabetic Knowledge Scale developed by Arunneatara (2005) was used to measure diabetic knowledge in this study. The initial content validity was accepted by the panel of experts including two endocrinologists, two nurse instructors who were experienced in the area of diabetes care, a nurse instructor who was expert in psychology, and a nurse instructor who was expert in behavioral science (Arunneatara, 2005). In this study, the reliability coefficient of the Diabetic Knowledge Scale was tested in 20 diabetic patients by using Kuder-Richardson 20 (K-R 20) = .77. The final test in 147 diabetic patients reported the K-R 20 at .74.

The accuracy and precision of laboratory measurement were tested by the quality control section of the central laboratory from the medical science center, Chonburi. The sphygmomanometer and balanced beam scale were calibrated by the clinical instruments testing center of Prapokklao hospital, Chanthaburi.

Protection of Human Rights

Prior to the collection of data, approval of the proposal for the study and the instruments were approved by the Research Ethics Committee of the Faculty of Nursing, Chiang Mai University (see Appendix D). The researcher asked for permission and approval for the study proposal and the instruments from the Research Ethics Committee of community hospitals, Chanthaburi province.

The researcher gave a complete explanation and written description about the purposes, processes of the study, methods, potential risks and benefits of participation, and the protection of confidentiality of nursing staff, health care providers, and people with type 2 diabetes who met the inclusion criteria for this study. The researcher described objectives and processes of the study to them. Additionally, these diabetic patients were informed that they would be participating in a nursing program that was designed to encourage them to gain knowledge and skills for controlling their illness. They were assured about confidentiality and anonymity before signing the consent form. They had an opportunity to ask questions about the study before signing, and could refuse to participate or withdraw from the program at anytime.

The subjects in the control group also received a complete explanation and written description about the purposes and processes of the study, and the protection of confidentiality and anonymity. The researcher informed the control group that they received the usual nursing care given by nurses in a diabetic clinic. At the end of the program, the researcher provided a diabetes education class and the "Patient Personal Manual" for the control group (waiting list).

Data Collection Method

1). Data collection (as shown in Figure 2) began following the review and approval of the study by the Research Ethics Committee of the Faculty of Nursing, Chiang Mai University, and the Research Ethics Committee of the community hospitals (see Appendix D).

2). After approval was obtained, the nurse researcher contacted the director of the community hospitals. The purpose and procedure of the study were explained for health care teams.

3). The nurse researcher asked for permission to make initial contact with people with type 2 diabetes and introduced the study to those who met the inclusion criteria.

4). A complete verbal explanation about the study was given to the people with type 2 diabetes who met the inclusion criteria. People who agreed to participate in this study were asked to sign the consent form (see Appendix E).

5). People who agreed to participate in the experimental and control groups were asked to respond to the Diabetes Knowledge Scale and Quality of Life Scale (SF-36 version 2) by the research assistants who were trained by the researcher. Then, the researcher asked participants to have blood drawn for FPG, HbA_{1c}, and lipid profile. Body weight, height, and blood pressure were measured following the protocol by the research assistant. Demographic data were recorded for people in both experimental and control groups during the first week.

The Experimental Group:

1). The researcher set the appointment dates for the experimental group to participate in the program (10-15 people/group in either the diabetes education session or group discussions), and set the appointment dates for individual home visits.

2). Interventions were provided for the experimental group (as mentioned in the nursing manual) for promoting diabetes self-management of people with diabetes.

2.1) Small group diabetes education was taught by the researcher for the experimental group in the first week (2 hrs/group). One group was composed of 10-15 people. The class was provided for one group a day, three days a week. People were given the patient manual for self-management. The researcher demonstrated goal techniques through action plans, and promoted realistic individual goals setting.

2.2) The researcher provided four group discussions for 10-15 people/group at the 2nd, 4th, 6th, and 8th week. The group discussion was approximately 1-1 hr 30 min/ session. It was provided for one group a day, three days a week. The program contains: a) promoting and formulating action plans and realistic individual goal setting, b) skills mastery: promoting confidence in ability to undertake diabetes self-management, actions for controlling illness (meal planning; medicine taking, exercise/physical activities and foot care; signs and symptoms monitoring; and meditation techniques for stress reduction), c) modeling: promotion of successful patients who perform appropriate behaviors as models and demonstration of desired behaviors, and d) physiological and emotional arousal: reinterpretation of their symptoms and help them to increase their efficacy in dealing with the disease; and e)

persuasion by encouraging patients to make lifestyle changes. Sharing experience to group members was promoted.

2.3) The researcher provided two individual sessions (home visiting at the 3rd, and 6th week), approximately 30 - 45 min/session. The researcher promoted: problem-solving; anticipation of barriers and maintenance of new behaviors; continuing education; ongoing reinforcement; and promotion of adjustments for goal attainment. People with diabetes were encouraged to achieve more than they had been accomplishing. The researcher supported making life style changes, and regularly made contact throughout the follow-up period

3). Using the Diabetes Knowledge Scale, Quality of Life Scale (SF-36) Thai version 2, body weight, height, and blood pressure were checked following the protocol by the research assistants who were trained by the researcher. The FPG, HbA_{1c}, and lipid profiles were measured by a technician following the protocol at the 24th week after initiation of the program.

The Control Group:

1). The control group received the diabetes education and the patients' manual after finishing the program.

2). The researcher set appointment dates for the control group to participate in the program (10-15 people/ group in the diabetes education session to begin after finishing the program).

3). People in the control group received the usual care from nurses at the diabetic clinic during the 24 weeks of the program.

4). Using the Diabetes Knowledge Scale, Quality of Life Scale, (SF-36) Thai version 2, body weight, height, and blood pressure were checked by the research assistants following the protocol. The FPG, HbA_{1c}, lipid profiles were measured by a technician following the protocol at the 24th week after entering the program.

5). Diabetes education was provided by the researcher for the control group (waiting list) after the 24th week (2 hrs/group). One group composes of 10-15 people. The class was provided for one group a day, three days a week. All participants received a patient manual for self-management, called *"Living Well with Diabetes"*. The researcher demonstrated goal setting techniques through action plans, and promote realistic individual goals setting. Additionally, the researcher explained how to use the patient manual (see *Figure* 2.)

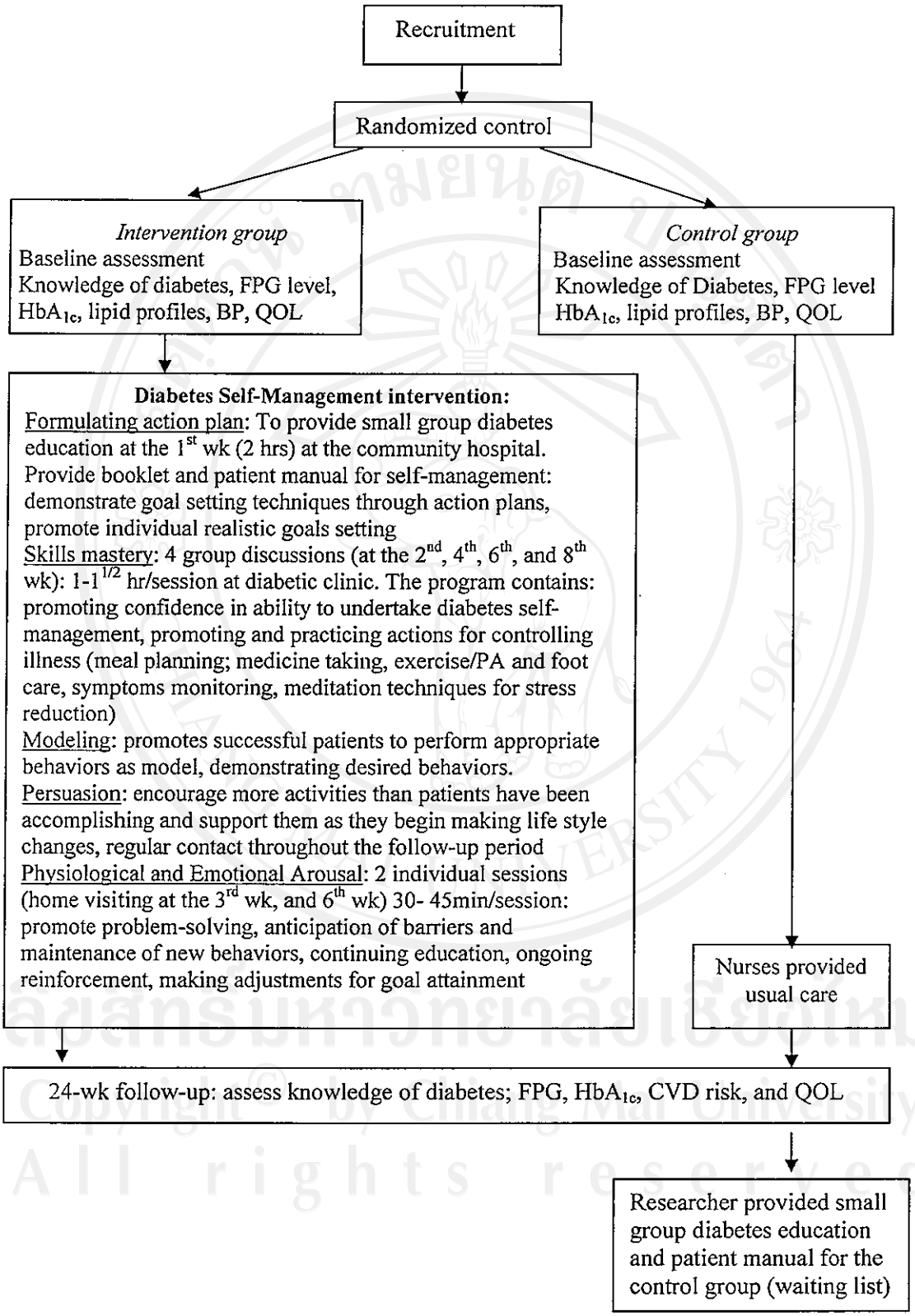

Figure 2. Data collection for diabetes self-management program

Data Analysis

1) The demographic and clinical characteristics of participants were summarized using frequency distribution, percentage, mean, and standard deviation. Chi - square, Fisher's Exact test, independent sample *t* - test, rank sum Mann Whitney - U were used to examine the difference of characteristics between the experimental and control groups at baseline.

2) Paired *t*-test was used to examine the difference in the mean scores of diabetes knowledge, glycemic control levels, CHD risk, and QOL of people with type 2 diabetes between before entering the program and at the end of the program (24 weeks) in both experimental and control groups. Prior to analysis the assumption of normality was tested (see Appendix F).

3) Analysis of covariance (ANCOVA) was used to examine the difference in the mean score of knowledge of diabetes, FPG and HbA_{1c} level, CHD risk, and QOL of people with type 2 diabetes between experiment and control groups by adding the pre-test and age as covariate since the results of baseline test showed borderline difference of age between group ($p = .053$), and age is a predictor of glycemic control and coronary heart disease.