CHAPTER 3

METHODOLOGY

This chapter presents a description of research design, population and sample, research setting, research instruments, human rights protection, data collection procedures, and data analysis.

Research Design

This study applied a randomized control trial design with two groups (self-management support group and usual care group), to examine the effect of a self-management support program on eating behaviors, physical activity, and metabolic control for people with metabolic syndrome. Eating behaviors, physical activity, and metabolic control were examined before and after receiving a self-management support program. The differences in eating behaviors, physical activity and metabolic control were also examined between the people who received a self-management support program and those who received usual care. The sample was recruited based on inclusion criteria, then randomly assigned to either the experimental group or comparison group using the mixed permuted block four and allocation concealment method. Randomization was performed by a person blinded to the study. Therefore, the researcher and participants were unaware of the assigned randomization and all participants did not know which group they are. Data for both groups was collected at

baseline, the end of the program, and three months after the end of the program. The research design was presented as follows:

$$
\begin{array}{llll}
E & O_1 & X_1, X_2\ldots\ldots X_6 & O_2 & O_3 \\
C & O_1 & & O_2 & O_3
\end{array}
$$

R
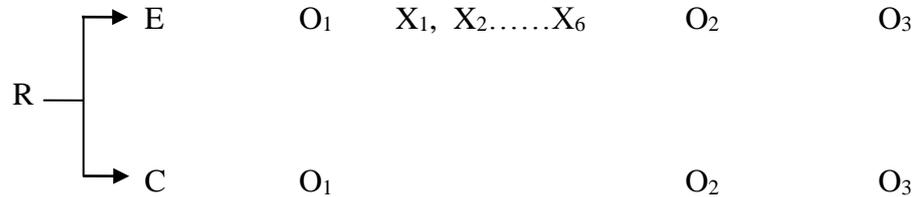
E	= Experimental group
C	= Comparison group
R	= Randomization
O_1	= Measurement at baseline
$X_1, X_2\ldots X_6$	= Self-management support program 6 sessions
O_2	= Measurement at three months after entering the program
O_3	= Measurement at three months after completing the program

Variables: The independent variable is a self-management support program for people with metabolic syndrome. Dependent variables include eating behaviors, physical activity, and metabolic control such as waist circumference, blood pressure level, fasting blood glucose level, plasma triglyceride level, and plasma high-density lipoprotein cholesterol level. Extraneous variables include age, gender, educational level, occupation, family income, the number of MetS parameters, and medication.

Population and Sample

Population

The accessible populations of this study were people with metabolic syndrome who received treatment of care in the hospitals in Chiang Mai province, Thailand.

Sample

People with metabolic syndrome, both men and women, who met the following criteria

Inclusion criteria. The participants were recruited into the study when they had; a) aged between 50 to 75 years; b) having at least three of the five criteria of metabolic syndrome following the modified National Cholesterol Education Program Adult Treatment Panel III criteria (2005): high waist circumference (> 90 cm in men, > 80 cm in women), high blood pressure level ($\geq$ 130/85 mmHg or use of antihypertensive medication), high fasting plasma glucose level ($\geq$ 100 mg/dL or treatment of diabetes mellitus), high plasma triglyceride levels (> 150 mg/L), and low high-density lipoprotein cholesterol levels (< 40 mg/dL in men, < 50 mg/dL in women); c) being able to read, write, and comprehend Thai language; and d) willing to participate in the program.

Exclusion criteria. The participants were excluded from the study if they had the following conditions; a) having a history of coronary artery disease, myocardial infarction, or heart failure; b) having co-morbidities that affect physical

activity and/or need for additional diet, including musculoskeletal impairment, asthma, chronic obstructive pulmonary disease, gout, renal disease, cerebrovascular disease, peripheral vascular disease, diabetes which requires insulin, hepatic impairment, and thyroid disease; c) having systolic blood pressure more than 160 mmHg and diastolic blood pressure more than 120 mm.Hg; and d) having fasting blood sugar level more than 300 mg/dl.

Discontinuation criteria. The participants would be terminated from the study if they had the following conditions: a) having a new onset of ischemic heart disease, myocardial infarction, or heart failure; b) having any condition that rendered them unable to participate in group session; and c) could not join all sessions of intervention.

Participants were randomly assigned into a self-management intervention group or a usual care group.

Sample Size

An estimated sample size for this study was calculated using the formula of Thato & Dusitsin (2008) with level of significance of α =.05 (probability of type 1 error) and power of .90

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

n = estimated sample size

Zα = 1.64 for significance level at .05 (95% confidence desired)

Zβ = 1.28 (10% beta error, 90% power desired)

δ = effect size

σ = standard deviation

The effect size to be used for calculation was from the study of Fan and Sidani (2009) who conducted a meta-analysis to examine differences in knowledge, self-management behaviors and metabolic control associated with various diabetes self-management education (DSME) intervention elements. From that study the effect sizes for behavioral types of DSME interventions with respect to metabolic outcomes was .63. Therefore, the sample size was computed and the result showed 43 participants per group were needed.

$$n = \frac{(1.64 + 1.28)^2 \times 2}{(0.63)^2} \; ; \qquad n = 43$$

However, the previous similar study in Thailand reported the attrition rate of a self-management intervention was 6.37% (Wattana, Srisuphan, Pothipan, & Upchurch, 2007), therefore, the sample size was estimated for 7% attrition rate.

$$n \;=\; \frac{43}{93} \; X \; 100 \qquad\qquad =\; 46$$

As a result, the sample size needed for this study should be approximately 92 participants, with 46 participants in each group.

Recruitment and Randomization Procedures

Recruitment procedures were performed at three hospitals in Chiang Mai province, Thailand. The researcher reviewed the medical history records prior to

enrolling the participants in the Diabetic and Hypertension Clinic. People who met the inclusion criteria were approached to participate in the study. Potential participant received an information sheet describing: the study purpose; what would be involved for research participants; assurance of confidentiality and anonymity issues, and the ability to withdraw at any time without consequences. People who were willing to enroll in the study were asked to sign the consent form and were randomly assigned to either the experimental group or the comparison group.

Randomization Procedures. People in each research setting (three settings) were randomly assigned into a self-management support program group or a standard care group. The randomization technique which was used to maintain good balance of the experimental and comparison participants was the mixed permuted block 4 and allocation concealment. Blocks having equal numbers of A and B (A = experiment and B = comparison) were permuted for the order of treatment. A block of four has six different possible arrangements of two "As" and two "Bs": AABB, ABAB, ABBA, BBAA, BABA, and BAAB. A random number sequence was used to choose a particular block, which set the allocation order for the first four subjects. Similarly, a treatment group was allocated to the next four patients in the order specified by the next randomly selected block. The process was then repeated. Permuted block randomization ensured treatment group numbers were evenly balanced at the end of each block. A nurse who was not involved in the study arranged randomization lists and kept randomization lists in envelopes. The envelopes looked identical and each had a sequential number on it. Inside each envelope was the treatment allocation. After assessing eligibility and consent, the next envelope in sequence was opened.

Research Setting

The research setting in this study consisted of two urban areas including the Chiang Mai Municipality area, Kawila subdistrict, and another one located in the Mae Rim district. People with metabolic syndrome who were chosen to recruit prospective participants come from the Diabetes and Hypertension Out Patient Department at three hospitals in these urban areas and they live around those hospitals. In this study, the program was implemented in the community. The places where the program was implemented are close to their houses including temples, community pavilions, or community leaders' house.

These communities are composed of higher population density, and modern buildings. In addition, there are department stores, supermarkets, markets, and convenience stores. There are also exercise areas which were provided by local administration close to participants' houses such as temple courtyards, parking lots or health parks.

Instrumentations

The instruments that were used in this study included the Demographic Data Form, the 7-day Food Diary, the Physical Activity Logbook, the OMRON IA2 Automatic Blood Pressure Monitor, and an Anthropometry Tape.

The Demographic Data Form

A Demographic Data Form was designed to obtain information on age, gender, educational level, occupation, family income, medication, waist circumference, blood pressure, fasting blood sugar, plasma triglyceride, and plasma HDL cholesterol at baseline.

A 7-day Food Diary

A 7-day Food Diary was used for collecting data on eating behaviors from which the daily nutrient intake covering carbohydrates, protein, fat, cholesterol, fiber, sodium, and sugar. This instrument was developed from Dietary Assessment-Weight Food Diary by Livingstone et al. (1992).

Participants were asked to complete a 7-day food record and to record all food and drink consumed at home or outside home. Participants were asked to record food and beverage consumed in the past seven days. The details of consumed food and beverage were on brand names, place, time of consumption, description of preparation and cooking method, and recipes for composite dishes. Food portion sizes were measured using cups, tablespoons, teaspoons, grams, and pieces. All participants were provided with measuring cups and spoons.

All daily nutrient intakes were calculated using the INMUCAL-Nutrients software program, developed by the Institute of Nutrition, Mahidol University, Thailand (2007).

The criterion validity of the 7-day Food Diary was estimated using the reference data of the Dietary Questionnaire for Epidemiological Studies (Cancer

Council of Victoria, 2005). The high positive correlation between this instrument and the criteria used was demonstrated ($r = 0.89$ for starch, 1.00 for meat, 1.00 for snack and beverage, .61 for fruit and vegetables). The 2-week test-retest reliability of the 7-day Food Diary ranged from .70 to .85 and all scales possessed acceptable levels of reliability coefficient (Frank-Strombors & Olsen, 2004).

Physical Activity Log

A physical activity log was used for collecting data on the daily physical activity. This instrument was modified from the Community Health Activities Model Program for Seniors (CHAMPS) by Stewart et al. (2001). The physical activity log book provided a detailed record of an individual's physical activity on a daily basis. Participants recorded all activities including occupation, during, household, transportation, and leisure-time for 7 consecutive days. The lists of activities were calculated as daily metabolic equivalents (MET) value (Met-h day). The sum of the MET value was divided into 4 categories.

MET value (Met-h day)	Level
32-35.9	Inactive
36-38.9	Light active
39-42.9	Moderate active
≥ 43	Very active

The criterion validity of the Physical Activity Log was shown by a statistically significant strong relationship with the Physical Activity Questionnaire

(Stewart et al., 2001) ($r = .901$, $p = .050$). The 2-week test-retest reliability of Physical Activity Log Book was evaluated from which a strong correlation of .93 and possessed acceptable levels of reliability coefficient (Friedenreich, Courneya, & Bryant, 1998).

The OMRON IA2 Automatic Blood Pressure Monitor

The OMRON IA2 Automatic Blood Pressure Monitor was used for measuring blood pressure. Blood pressure was taken in the upper arm. The standard method for measuring blood pressure based on the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) (National Heart, Lung, and Blood Institute, 2004). A mean value was calculated from 3 measurements. Systolic blood pressure less than 130 mmHg and diastolic blood pressure less than 85 mmHg are recommended as a good blood pressure control.

The criterion validity of this instrument was estimated by comparing the OMRON IA2 automatic blood pressure monitor with sphygmomanometer (Mercury manometer). The result of bivariate correlation of systolic blood pressure was a strong positive relationship ($r = .927$, $p = .000$). The result of bivariate correlation of diastolic blood pressure was also a strong positive relationship ($r = .727$, $p = .004$). The accuracy was within 5 mmHg of each other.

The Olympus AU 400 Fully Automated Analyzer

This instrument was used for measuring fasting blood sugar (FBS), plasma triglyceride level and plasma HDL cholesterol level. The blood tests were performed by a medical technician at the Faculty of Medical Technology lab, Chiang Mai University. The normal range of fasting blood sugar is below 100 mg/dl, triglyceride level is below 150 mg/dL, and HDL cholesterol level is more than 40 mg/dL in men and more than 50 mg/dL for women.

Anthropometry Tape

An Anthropometry Tape was used for measuring waist circumference. Measurements followed the Waist Circumference Measurement guideline (International Chair on Cardiometabolic Risk, 2009). The tape was placed horizontally and wrapped all around the iliac crest, over minimal clothing and at the end of expiration, and was recorded to the nearest cm. Waist circumference below 80 cm in women or below 90 cm in men is considered as non obese, and an indicator of good metabolic control.

Intervention Description

The intervention was the Self-management Support Program for People with Metabolic Syndrome (SSPPMS). The SSPPMS was developed based on self-management using the 5A's model of Glasgow and colleagues (2002). The Program aimed to increase knowledge, self-management skills and confidence to effectively manage behavioral change (eating behaviors and physical activity). The SSPPMS also focused on supporting the experimental group to meet the goal of controlling metabolic indicators through eating behaviors and physical activity. The process covered: setting goals and achieving goals; developing self confidence leading to behavioral change; acting to change behavior and control metabolic indicators; monitoring progress; solving problems of personal self-management plans; offering social and environmental support and encouraging through continuous contact and maintenance behaviors.

The strategy for controlling MetS is comprised of five A activities: (1) *Assess*: assessment of knowledge, barriers to change behaviors, confidence to change, problem solving ability and target behaviors; (2) *advise*: provision of information about health risks and benefits to change and support behavioral changes; (3) *Agree*: collaboration between patients and health care providers on setting realistic goals based on patient's interest and confidence in their ability to change behavior and enhance confidence to change; (4) *Assist* patients' adjustment of goals and action plans, identify barriers, choose strategies or skills, offer social or environment support and increase confidence by using motivational interviewing techniques; and (5) *Arrange*: specify a plan for follow-up, ongoing support and maintenance behaviors.

In conjunction with the program, a motivational interviewing technique (Miller, & Rollnick, 2002) has been used to assist people to increase self-confidence and gives strategies to change their unhealthy behaviors by helping them recognize and resolve discrepancies between their present behavior, and their future goals and values. The details of the process of five activities are showed in Table 3-1.

Table 3-1

A Five A's Activities

Activities	Method	Tools
1. Assess		
1.1. Demographic data	- Interview patient to get the information on their	- The Demographic Data Form
1.2. Knowledge about metabolic	medical history, metabolic risk factors, current eating	
syndrome	behaviors and physical activity, and medical treatment.	
1.3. Barriers to change behaviors	- Assess the participant's knowledge about metabolic	- The Interview Form
1.4. Confidence to change behaviors	syndrome.	
1.5. Problem solving ability	- Identify target eating behaviors and physical activity.	- The group discussion record
1.6. Target behaviors	- Identify the health related risks and share with the	
	participant.	
	- Assess participant's goals and action plan.	- Goal and Action Plan Sheet
	- Identify problem and barriers to improve eating	- Motivational interviewing
	behaviors and increase physical activity.	techniques

Table 3-1 (continued)

Activities	Method	Tools
	- Review accomplish and problem.	- The group discussion record
	- Estimate patient's confidence level every follow-up visits. .	- The confidence scale

2. Advice

2.1. Information includes metabolic syndrome, metabolic syndrome management (diet and physical activity), metabolic control, and self-management skills.	- Arrange small group session with three to four members in four education and discussion sessions. - Provide educational booklet to participant.	- Power point and flip charts - A Metabolic Syndrome Booklet - Food Exchange Booklet
2.2. Supporting behavioral change		- Physical Activity Booklet - Self-management Skill Guidebook

Table 3-1 (continued)

Activities	Method	Tools
	- Explain how to self-monitor diet intake and physical activity and provide the self-monitoring tools.	- Food diary - Cups and spoons measurement for managing diet portion size - Physical activity Log
	- Get the participants to acknowledge that they need to change. The importance of behavior change in prevention or delaying the onset of complications is highlighted.	- The group discussion record
	- Discuss physical activity, diet control, metabolic control, and self-management. Benefits of behavioral change and its relation to their health were emphasized.	
	- Discuss the problem or barriers to do physical activity and control diet intake, and the techniques used	- The scenarios of problem situation of diet and

Table 3-1 (continued)

Activities	Method	Tools
	- Discuss actual problem situation, define barriers together with participant, and help participant how to overcome it. - Provide feedback with all activity records.	physical activity
3. Agree 3.1. Collaboratively set goals	- Negotiate with participant about goal and action plan. - Writing goals and action plans to accomplish goals on the goal and action plan sheets.	- Goal and action plan sheets
4. Assist 4.1. Adjusting goal and action plan 4.2. Choosing strategies or skills 4.3. Motivating confidence	- Help participant to set goals and action plans based on the patient's conditions, interest and priority. - Help participant to adjust patient's goals and action plans when barriers are identified.	- Goal and action plan sheets

Table 3-1 (continued)

Activities	Method	Tools
4.5. Offering social or environment support	- Support participants to feel they have a role in setting the goals and discussion. - Reinforce self-monitoring in physical activity and diet intake. - Provide diet and physical activity counseling based on the associated findings. - Motivate participant to persistent action for achieving their goals and to overcome barriers to do physical activity and diet control. - Motivate participants to do physical activity and to persist with the change over time.	- Motivational interviewing techniques

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Table 3-1 (continued)

Activities	Method	Tools
	- Offer resources and materials or link to community resources for supporting physical activity and diet control.	
	- Encourage participants to seek supports from friend, family, and community.	
	- Promote self-management skills.	
	- Motivate confidence when participant's confidence score is below 7.	
5. Arrange		
5.1. Follow-up plan	- Set follow up plan.	-A follow-up card
5.2. Ongoing support and maintenance	- Remind follow up plan with follow up card.	
	- Arrange support and maintenance.	

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Program Content and Materials

The SSPPMS lasted three months, and included a two hour session in each of the first four weeks, and then one session in months two and three. Small group sessions were held with three to four members in four education and discussion sessions (120 minutes/session), lead by the researcher.

The first session (Week 1). This session focused on the provision of information about MetS, MetS management (diet and physical activity), metabolic control, and self-management skills. Participants received the package materials of the self-management support program. In the first 30 minutes, participants were given an orientation program. Question and answers were encouraged by the researcher. Next, for fifteen minutes, participants were asked about demographic data. Then, participants discussed metabolic syndrome for fifteen minutes. The next session was group education which was approximately 45 minutes. Participants received information including metabolic syndrome, metabolic syndrome management (diet and physical activity), metabolic control, and self-management skills. At the end of the session, an open discussion to clarify misunderstandings was held. Questions were answered by the researcher. The researcher made an appointment and wrote the date on the follow-up card.

The second session (Week 2). This session involved goal setting, creating an action plan, and self-monitoring progress. Activities included a review of target eating behaviors and physical activity, effective goals, and practicing writing goals and an action plan. Participants, together with the researcher, set goals and an action plan for eating and physical activity based on an individual's conditions, interest and

priority. The researcher asked participants to write goals on the goal and action plan sheets. Next, the researcher and participants discussed each individual action plan and wrote the action plan on the goal and action plan sheets. The researcher asked participants to assess confidence in doing the action plan using the confidence scale. The researcher motivated confidence when participant's confidence score was below seven by using motivational interviewing techniques. For the next 60 minutes, participants additionally learned how to record dietary consumption and physical activity, and were given the food exchange book, measuring spoons and cups, a food diary, a physical activity booklet, and a physical activity log. The researcher offered food choices based on a daily intake of 1,600 to 2,000 calories. When participants chose the total energy per day dependent on body mass index or whether they were trying to lose, gain or maintain their weight, the researcher determined the number of food servings per day for each food group. With regards to physical activity, the researcher allowed participants to choose the type of exercise that they would like to do. The exercise chosen were enjoyable, convenient and accessible based on the Physical Activity Booklet. The researcher made an appointment and wrote the date on the follow-up card.

The third session (Week 3). This session focused on strategies for problem solving. The activities included accomplishments and problems encountered during implementation of techniques learned in the second session, the learning experiences and strategies used, practicing strategies for dealing with barriers using the scenarios of problem situation of diet and physical activity, and adjusting goals and action plans. The researcher assessed participants' goals and action plans. If participants could not follow the action plan, each problem was discussed and

problem-solving skills were promoted to overcome barriers. Goals and action plans could be adjusted. Motivational interview techniques were used during discussion. The researcher encouraged participants to continue to use self-management skills to do healthy eating behavior and physical activity. The researcher asked participants to assess confidence in doing healthy eating behavior and physical activity. The researcher also made an appointment for a follow-up session in the next week and wrote the date on the follow-up card.

The fourth session (Week 4, Month 2, and Month 3). This session emphasized the promotion of self-management skills and support to maintain healthy eating and increasing physical activity. Activities included reviewing accomplishments and problems encountered by a participant's performance of self-management techniques learned from session two and three, discussion of the problems and the techniques used, feedback with all activities records, and encouragement to moving goals towards maintaining healthy eating and increasing physical activity. The researcher showed the results of the daily dietary intake and daily energy expenditure which was analyzed from the 7-day food diaries and physical activity logs for each individual and gave feedback through focusing on attainment. Participants participated in group discussion aiming to obtain information related to goal attainment, action plan setting, problem and barriers and the results of self-monitoring. The researcher also motivated participants to retain physical activity and diet control for achieving the goals. The researcher made an appointment for a follow-up session in the next four weeks and wrote the date in a follow-up card. The activities in session four were continued once again in month two and three (see Table 3-2).

In each session, participants had their confidence level assessed for performing healthy eating behaviors and physical activity. Participants, whose confidence score was lower than seven, were re-motivated by the researcher using motivational interviewing techniques.

Materials.

Metabolic Syndrome Booklet. The Metabolic Syndrome Booklet is health information about metabolic syndrome for patients, family members, and other caregivers. This booklet describes definitions, metabolic risk factors, progression of the disease, signs and symptoms of MetS, diagnosis and treatment, metabolic syndrome management, and metabolic control. This booklet was given to participants in the first week.

Food Exchange Booklet. The Food Exchange Booklet is the determinant of a daily food plan based on unit for exchanges of various food types. The nutrient content of each item on a food exchange list is calculated according to its serving size, so that items in the same category have approximately the same nutritional value. One serving size of a food in a category can be exchanged for one serving size of any other food in the same category. The categories include starches, meat and meat substitutes, fat, fruit and vegetables, beans and legumes, and milk and dairy. This booklet was given to participants in the first week.

Physical Activity Booklet. The Physical Activity Booklet is designed to help people with metabolic syndrome maintain an active lifestyle. This booklet includes basic information about daily physical activity, safe tips, and appropriate

suggestions for getting more physically active, and problem solving of common issues. This booklet was given to participants in the first week.

   Self-management Skills Guidebook. The Self-management Guidebook is composed of self-management strategies for developing self-management skills. The topics in this guidebook include an overview of self-management, setting goals and an action plan, problem solving, self-monitoring, self-confidence, social support, emotional control and relapse prevention. Each topic is composed of content, situational dialogues and exercises. This booklet was given to participants in the first week.

   The validation of a self-management support program and the materials were evaluated and approved by three experts including one nurse expert in diabetes self-management and two doctors of cardiology (see Appendix D). These materials were revised according to their comments and suggestions.

Table 3-2

The Summary Protocol of a Self-management Support Program

Time	Assess	Advise	Agree	Assist	Arrange
Week 1	*Session 1 : Educational Information*				
	Patient's demographic data Knowledge about MetS	Educational information about MetS, metabolic control, and self-management skills			Set appointment and write the date in the follow-up card
Week 2	*Session 2 : Goal Setting and Action Plan*				
	Target eating behaviors and physical activity Confidence to improve eating behaviors and increase physical activity	How to self-monitor physical activity and diet intake Provide physical activity log, food diary and measuring spoons and cups	Collaborative goal setting and action plan	Write goals and action plan Motivate confidence in writing goals and action plan and in ability Motivate confidence in ability to increase physical activity and eating control	Set appointment and write the date in the follow-up card
Week 3	*Session 3 : Problem Solving*				
	Patient's goals and action plan Problem and barriers to improve eating behaviors and increase physical activity Confidence to improve eating behaviors and increase physical	Problem solving	Collaborative goal setting and action plan	Adjust patient's goals and action plans Reinforce self-monitoring in physical activity and diet intake Diet and physical activity Counseling Motivate patient to persist action and confidence Offer social or environment support	Ongoing support and maintenance Appointment and write the date in a follow-up card
Week 4,	*Session 4 – 6 : Ongoing Support and Maintenance*				
2nd and 3rd months	Review accomplish and problem	Discuss of the problem and the techniques used Feedback with all activity records		Promote self-management skills and support	Appointment and write the date in a follow-up card

Protection of Human Subject

The study was approved by the Research Ethical Committee of Faculty of Nursing, Chiang Mai University. In addition, permissions for data collection were obtained from the directors of the three hospitals in Chiang Mai province.

A consent form was obtained from participants before data collection. The researcher gave a complete explanation and written description of the purposes, processes, methods and potential risks of the study and identified the benefits of participation, and the protection of confidentiality to participants. The researcher also informed the participants that their participation was voluntary and they could withdraw consent to participate at any time without affecting their treatment and hospital utilization. In addition, the participation in this study was free of charge. All participants received full compensation for costs of transportation. Additionally, the researcher assured that data were collected confidentially and de-identified in any reporting. Only the patient number and patient initials were recorded. All personal information was handled in strictest confidence and accordance with standard data protection laws. The data will be destroyed after the dissertation is published. After data collection was completed, the researcher provided all materials of the program to the comparison group. The researcher also provided contact address and telephone number to all participants so they could directly contact the researcher if they needed further information.

Data Collection Procedures

Data collection procedure was conducted for a 6-month period as follows:

1) Data collection began after getting approval from the Research Ethics Committee of the Faculty of Nursing, Chiang Mai University.

2) The researcher contacted the director of the three hospitals in Chiang Mai province and explained the purposes and procedures of the study. Permission was granted to collect the data for the study.

3) The researcher selected prospective participants from patient records by reviewing patient history of hyperglycemia, hypertension, dyslipidemia, and obesity. Patients who met the inclusion criteria were asked to participate in the study and were given an appointment for full screening. Informed consent was obtained at that time.

4) The researcher randomly assigned the participants into experimental and comparison groups using the mixed permuted block four technique and allocation concealment. The experimental group received a self-management support program and the comparison group received standard care.

5) The researcher set the appointment date for blood sampling included fasting blood sugar, triglyceride and HDL cholesterol. All participants fasted for 10 hours before blood collection. Fasting allowed no food or drink, except water.

6) At baseline, the researcher collected blood samples and measured blood pressure and waist circumference. Moreover, the researcher advised participants how to record the food diary and the physical activity log. The researcher made an appointment date for getting back the food diary and the physical activity log within the next two weeks.

7) For the experimental group, the researcher provided the Self-management Support Program. The program duration was three months, and included six sessions; one a week for the first four weeks, then monthly for the second and third months (see Table 3-2). Posttest data and blood sample collection were performed after three and six months.

8) The researcher set an appointment date for collecting data and blood sample collection, and asked the experimental group to record physical activity and food consumption for seven days. Daily physical activity was recorded in the Physical Activity Log, and food consumption was recorded in the 7-day Food Diary.

9) For the comparison group, participants received treatment based on the 2010 Clinical Practice Guidelines in Diabetes, Hypertension, and Dyslipidemia Control of the Ministry of Public Health Thailand. It included health assessments, giving advice about their conditions, and treatment advice. Registered nurses who work at the diabetes and hypertension clinic provided health education. The education topics provided was mostly common health education including disease, medication, diet and exercise, and signs and symptoms to revisit hospital. Posttest data and blood sample collection were performed after three and six months.

10) The researcher set an appointment date for collecting data and blood sample collection, and asked the comparison group to record physical activity and food consumption for seven days. Daily physical activity was recorded in the Physical Activity Log, and food consumption was recorded in the 7-day Food Diary.

11) After data collection had been completed, the researcher provided the Metabolic Syndrome Booklets, Food Exchange Booklet, Physical Activity Booklet, and Self-management Skill Guidebook to the comparison group.
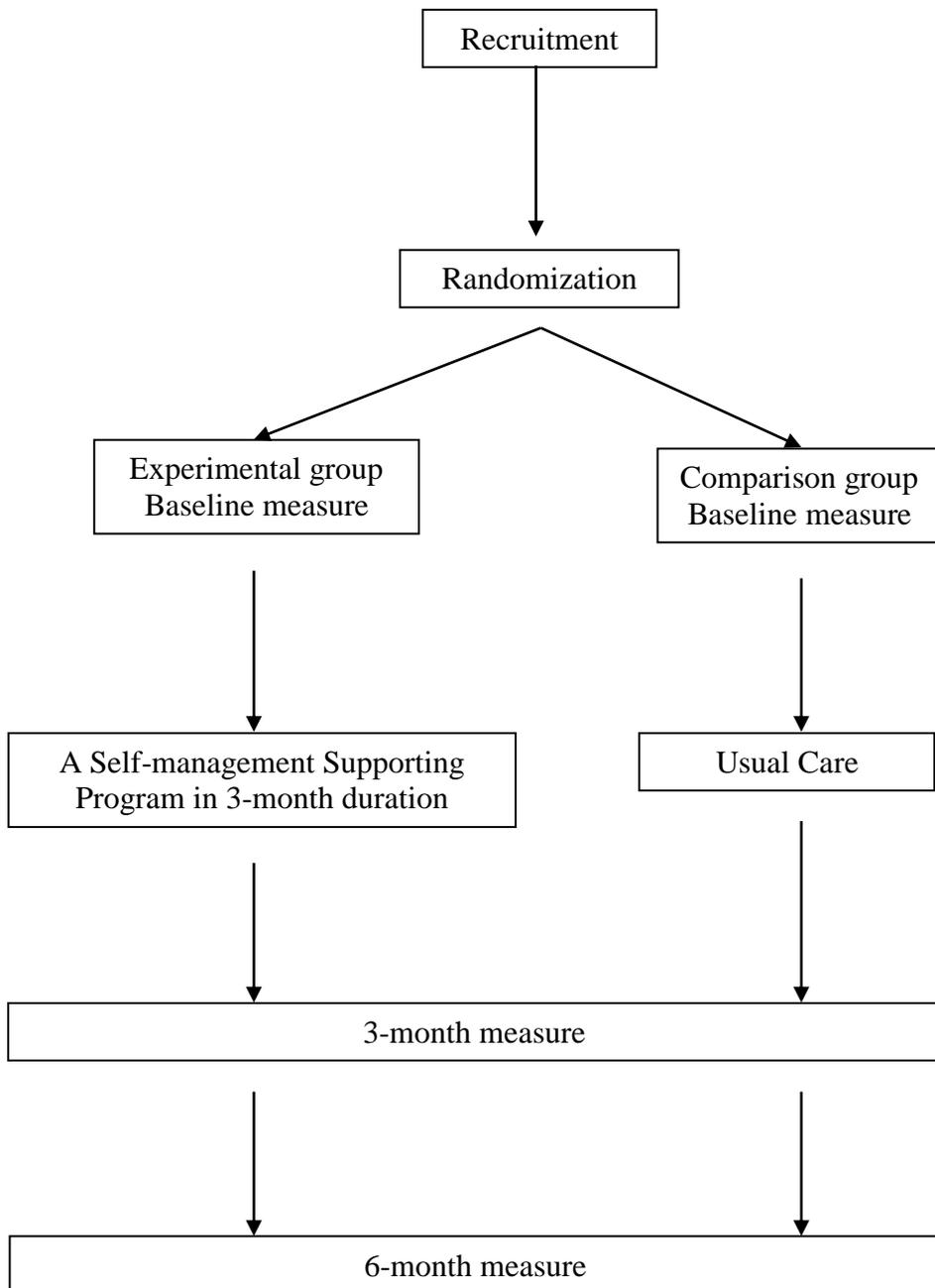
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        │ Experimental group │   │ Comparison group   │
        │ Baseline measure   │   │ Baseline measure   │
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   │ A Self-management        │   │ Usual Care       │
   │ Supporting Program in    │   │                  │
   │ 3-month duration         │   │                  │
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Figure 3. The summarization of data collection

Data Analysis

Demographic data and clinical characteristics were analyzed using descriptive statistics: frequency, percentage, mean and standard deviation. Independence t-test and chi-square test were used to examine the difference of characteristics between the experimental group and comparison group at baseline. In addition, Independence t-test was used to examine the difference of variables related to eating behavior, physical activity and metabolic control of the experimental group and comparison group at baseline.

To investigate the effects of the self-management support program, eating behaviors, physical activity and metabolic control were compared between the experimental and comparison group and between points of measurement. The analyses were followed in each specific objective.

Objective 1: To Compare Eating Behaviors, Physical Activity and Metabolic Control Between Baseline and Post-test of the Experimental and Comparison Groups

To investigate the effects of a self-management support program on eating behaviors, physical activity and metabolic control, one-way Analysis of Variance (ANOVA) with repeated measure was used to compare between baseline and post-test of the experimental and comparison groups at the end of the program and three months after the end of the program (baseline, 3 and 6 months). Prior to conducting one way ANOVA with repeated measure, the assumptions of ANOVA were tested by Mauchly's Test of Sphericity. Post-hoc analysis was used to determine the point of differences after repeated measure ANOVA.

Objective 2: To Compare Eating Behavior, Physical Activity and Metabolic Control Between the Experimental and Comparison Groups at each Point of Measurements

To investigate the effects of a self-management support program on eating behaviors, physical activity, and metabolic control, Mixed Model Analysis of Variance (ANOVA) with Repeated Measures was conducted to compare between the experimental and comparison groups and also the differences between points of measurement. Prior to data analysis, the assumptions of ANOVA were tested by Mauchly's Test of Sphericity. Multiple pairwise comparisons for these variables between each point of measurement were done using Independence sample t-test or paired sample t-test.