CHAPTER 3

METHODOLOGY

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

Research Design

A descriptive, cross-sectional, predictive correlation design was used to identify predictors and test a causal relationship between social support, patient-provider communication, knowledge of hypertension, health belief, perceived self-efficacy and adherence to therapeutic regimens in persons with hypertension.

Population and Sample

Population

The target population for this study was Thai persons with essential hypertension who attended a hypertension clinic in one of the community hospitals in Lampang province, Thailand.

Sample and sample size

The samples of this study were randomly selected from persons with hypertension who attended a hypertension clinic in one of four selected community hospitals in Lampang, Province. The inclusion criteria that were used for selecting participants of this study included: 1) age 35-59 years 2) having been diagnosed with essential hypertension for at least 6 months 3) taking at least one antihypertensive drug 4) having no symptoms which could interfere with their ability to respond to the questionnaires 5) being able to read and write the Thai language and 6) willing to participate in the study.

The sample size was estimated by using power analysis, effect size and 13 observed predictor variables from the hypothesized model. Before calculating the number of subjects required, the estimated population effect size was calculated using the following formula (Polit & Beck, 2004).

$$\gamma = \frac{R^2}{1- R^2}$$

A value of R^2 = .06 at a small level was used to estimate population effect size where the value of R^2 = .02-.12 was small, R^2 = .13-.29 was moderate, and $R^2 \geq$ .30 was large (Polit & Beck, 2004). Substituting R^2 = .06 in to the formula, the researcher found that the estimated population effect size in this study (γ) was .064.

Next, the following formula was applied:

$$N = \frac{L}{\gamma} + K + 1$$

Where N = estimated number of subjects needed

L = tabled value for the desired α and power

k = number of predictors

γ = estimated effect size

The power was the capacity of the study to detect differences or relationships that actually exist in the population. The minimum acceptable power for a study was 0.8 (Burns & Grove, 2005). The function of the significance level (α) was to control type I errors. The determined power and desired α in this study were 0.8 and .05 respectively. There were 13 predictors including 4 observed variables from health belief and social support, 3 observed variables from patient-provider communication and one observed variable from knowledge of hypertension and perceived self-efficacy. The table value for *L* when α = .05, power = .80 and 13 predictor variables was 17.78 (Polit & Beck, 2004). Substituting values into the formula, the researcher found that estimated sample size in this study was 292. The researcher planned for a dropout rate by adding 10% of estimated sample size, thus the minimum of 321 subjects was the sample size of this study.

Multi-stage random sampling method was used to obtain the required sample. The steps to obtain the subjects were presented as follows:

1. A simple random sampling technique was used to select four hypertension clinics from 12 community hospitals in Lampang province. The community hospitals were grouped as northern, eastern, western and southern zone. Then, one community hospital was selected at random from each zone of community hospitals. Thus, four community hospitals were used to obtain the subjects.

2. A simple random sampling was used to obtain the subjects who met the inclusion criteria for the study. The subjects in each hospital were selected at random from the names listed when they attended the hypertension clinic. Eighty subjects from three hospitals and 81 form one hospital were taken to participate in the study.

Research Setting

The data were collected at 4 hypertension clinics at the outpatient departments of community hospitals in Lampang Province, Thailand including Maemoh Hospital, Kokha Hospital, Sobprab Hospital and Chaehom Hospital. The community hospitals have 30-60 in-patient beds. These hospitals provide health care services including curative care, health promotion, and disease prevention for people who live nearby in the responsibility area. The services for persons with hypertension are provided in the hypertension clinic in the outpatient department of each hospital. These clinics provide services 1-2 days per week from 8.00-12.00 am. There are 2-3 nurse practitioners who provide treatment including investigation, prescription, health education and consultation. When persons with hypertension have complications or need to adjust medication to control their blood pressure, they will be directed to visit a general physician.

Research Instruments

Seven instruments were used to collect data in this study. They were presented as follows:

The Demographic Data Form

This form was developed by the researcher to collect demographic data of the sample including gender, age, marital status, educational level, personal income, occupation, medical payment, living arrangements, duration of being diagnosed with

hypertension, in-patient admitted with hypertension or complications, complications of hypertension, the number of antihypertensive medication(type), type of antihypertensive medication, number of medications per day, number of time of medication used per day, the interval of follow- up and blood pressure level (Appendix A).

The Hypertensive Social Support Scale (HSSS)

The HSSS was used to measure the level of perceived support for performing recommended behaviors to achieve target blood pressure level among persons with hypertension. The items were modified from the Social Support Scale which was developed by Pongudom (2006) based on social support concept of House (1981) including emotional, appraisal, informational and instrumental support. The HSSS was modified by adding items about perceiving support of persons with hypertension to perform recommended behaviors from others. It measured 4 components of social support including emotional, appraisal, informational and instrumental support. The HSSS scale contained 20 items with a 4 rating scale ranging from 1 (not true) to 4 (strongly true). The HSSS was grouped into four types of social support including emotional support (6 items), appraisal support (5 items), information support (4 items) and instrumental support (5 items). The total score ranged from 20-80. Higher scores indicated better social support. The content validity of HSSS was performed by five experts and the value of SCVI of this scale was .85. The internal consistency reliability was applied to 20 subjects who met the same inclusion criteria of the study. The Cronbach's alpha coefficient was .84.

The Provider-patient Communication Scale (PCS)

The PCS was used to measure the patients' perception of provider's communication regarding to talking clearly, explaining medical care and responding to patients' concern. The original Provider-patient Communication Scale was modified from 2 scales including the communication subscale of the Interpersonal Processes of Care (IPC) (Stewart et al., 1999, as cited in Xu, 2005) and the doctor support subscale of the Chronic Illness Resources Survey (CIRS) (Glasgow et al., 2000, as cited in Xu, 2005). The PCS has been used for Chinese persons with type 2 diabetes and was translated into the Thai Language and modified to make the items appropriate for Thai persons with hypertension. The back-translation procedure was used after getting permission from the author (Appendix B). The first step was translating the instrument into Thai by the researcher and one expert (Appendix C). Back translation of the Thai version to English was performed in order to enhance equivalence by two bilingual experts (Appendix D). Finally, nine items were modified to improve a closer culture and context fit for persons with hypertension.

The PCS consisted of 9 items in 3 dimensions including general clarity (2 items), explanation of hypertension and medical care (4 items) and carefully listening to and responding to patients' problems and concerns (3 items). It used a 4-point Likert scale from 1 (never) to 4 (always). The total score had a range from 9-36 and the higher scores indicated better communication between patients and health care providers. The content validity of PCS was performed by five experts and the value of SCVI of this scale was .85. The internal consistency reliability was applied to 20

subjects who met the same inclusion criteria of the study. The Cronbach's alpha coefficient was .77.

The Knowledge of Hypertension Scale (KHS)

This scale was used to measure knowledge of hypertension including causes of hypertension, symptoms and complications, pharmacological and non-pharmacological management. The items were modified from the Hypertensive Knowledge Questionnaire developed by Limcharoen (2006). The items were changed to clarify the wording in order to exactly measure knowledge of hypertension. There were 24 items with a dichotomous scale including yes, no and don't know. A score of 1 was given to a correct response whereas score of zero was given to an incorrect response and don't know. The total score ranged from 0-24 and was used to indicate level of knowledge of hypertension. Higher scores indicated a higher level of knowledge of hypertension. The content validity of KHS was performed by five experts and the value of SCVI of this scale was .93. The internal consistency reliability was tested by using the Kuder-Richardson 20 (KR-20) in 20 subjects who met the same inclusion criteria of the study and reported to be .83.

The Health Belief for Hypertensive Patient Scale (HBHS)

This scale was developed based on Becker's Health Belief Model and used to measure the perceived susceptibility to induce complications, perceived severity of complications, perceived benefits of performing disease control behavior and perceived barriers to performing disease control behavior for hypertensive patients.

The HBHS was modified from the original scale developed by Riounin (2007). There are 28 items with a 4-point rating scale which contained 7 items of perceived susceptibility to induce complications, 6 items of perceived severity of complications, 6 items of perceived benefits and 7 items of perceived barriers. Items with positive meaning are coded on a 4 point rating ranging from 1 (not agree) to 4 (mostly agree) whereas items of perceived barriers of performing disease control with negative meaning are coded ranging from 4 (not agree) to 1 (most agree). The possible score ranged from 28-112 and the higher score indicated a more appropriate health belief. Persons with hypertension who had a high score of health belief indicated that they had a high level of perceived susceptibility to induce complications, perceived severity of complications, perceived benefits of performing disease control behavior and had a low level of perceived barriers of performing disease control behavior. The content validity of HBHS was performed by five experts and the value of SCVI of this scale was .84. The internal consistency reliability was applied to 20 subjects who met the same inclusion criteria of the study. The Cronbach's alpha coefficient was .89.

The Hypertensive Self-efficacy Scale (HSS)

This scale was used to assess the perception of persons with hypertension on their confidence to perform required recommendations including taking of antihypertensive medication, dietary modifications, weight control, physical exercise, avoiding risk factors, stress management and follow-up visit in order to control their own blood pressure. It was modified from the Perception of Self-efficacy Questionnaire developed by Kairoj (1999) based on theory of self-efficacy (Bandura,

1997). The HSS was modified by changing and adding some items to cover required behaviors. There were 26 items which consisted of taking of antihypertensive medication (6 items), dietary modifications (4 items), weight control (2 items), physical exercise (6 items), avoiding risk factors (4 items), stress management (2 items) and follow-up visit (2 items). The response to each item was on a 4-Likert scale ranging from 1 (less confidence) to 4 (most confidence). The total scores ranged from 26-104 and the higher the score the higher level of perceived of self-efficacy. The content validity of HSS was performed by five experts and the value of SCVI of this scale was .96. The internal consistency reliability was applied to 20 subjects who met the same inclusion criteria of the study. The Cronbach's alpha coefficient was .89.

The Hypertensive Adherence to Therapeutic Regimens Scale (HATRS)

This scale was used to measure the extent of agreement and performance of persons with hypertension about the recommended behaviors provided by health care providers including antihypertensive medication taking, dietary modifications, weight control, smoking cessation, physical activity, alcohol intake limitation, and stress management. This HATRS was modified from the Hypertensive Adherence Scale developed by Limcharoen (2006). The HATRS was modified by adding items about the attributes of agreement which consisted of alignment of patients' behaviors and health recommendations, mastery of new behaviors and health knowledge, ongoing collaboration with health care providers on treatment plan and patients' perceived ability to meet optimal blood pressure. There were 29 items including four attributes: alignment of patients' behaviors and recommendations (16 items), mastery of new

behaviors (4 items), ongoing collaboration with health care providers on a treatment plan (7 items) and patients' perceived ability to meet optimal blood pressure (2 items). The response of each item was measured on a 4-Likert scale ranging from 1 (not true) to 4 (strongly true). The total score ranged from 29-116 and the higher the score the higher the level of adherence to therapeutic regimens. The content validity of HARS was performed by five experts and the value of SCVI of this scale was 1.00. The internal consistency reliability was applied to 20 subjects who met the same inclusion criteria of the study. The Cronbach's alpha coefficient was .92.

Protection of Human Rights

Ethical principles were adhered to in this study. Prior to the collection of data, approval of the proposal and the instruments were provided by the Research Ethics Committee of the Faculty of Nursing, Chiang Mai University (Appendix F). In addition, permission letters from the Public Health Office of Lampang province and the directors of the four community hospitals were also obtained prior to collecting the data. After getting permission from the Public Health Office of Lampang province and the directors of the four community hospitals, data collection began. A letter describing the study, its purpose, methods, potential risks and benefits of participation and the protection of confidentiality were given to all the samples who met inclusion criteria. The subjects were informed that they had the right to refuse, to ask for clarifications, or to withdraw from the study at any time by continuing to complete the questionnaires and without having any effect on their treatment or service to themselves. The subjects were asked to sign the consent form after they

agreed to participate in the study. After getting informed consent, the subjects were asked to answer the questionnaires in a private area in the outpatients department and the researcher gave dessert for the subjects during answering the questionnaires.

To assure anonymity and confidentiality of the subject's information, a code number was used in place of each subjects' name and information given by the subjects were used for the purpose of the study and presented as a whole result. The document containing the subjects' identification was concealed in a locked file, which only the researcher was able to access.

Data Collection Procedures

All questionnaires used in data collection, and the procedures used to collect the data were executed as follows:

1. A letter asking for permission to collect the data from the Faculty of Nursing was sent to the head of the Provincial Public Health Office in Lampang province and the directors of the four community hospitals including Maemoh Hospital, Kokha Hospital, Sobprab Hospital and Chaehom Hospital. Once permission was granted, the researcher visited each of the community hospitals to introduce the purpose of the project to the director of that hospital and their health care teams working in the hypertension clinic before data collection started. Then, the researcher directly contacted the head nurse and health care team of the hypertension clinic to give more information about the research study for mutual understanding, obtaining permission to recruit the subjects and to plan the data collection procedure together

with the health care team who work in the hypertension clinic. Furthermore, the health care team was asked to provide a private area for the subjects in the study.

2. The researcher reviewed the medical records of all persons with hypertension at the hypertension clinic in each hospital to select potential subjects who met the inclusion criteria.

3. Eligible participants were randomly selected from the name list of the selected persons with hypertension and invited to participate in the study.

4. A good rapport was established between the researcher and each participant. The researcher introduced herself and clearly explained the purpose of the research, its benefits and their rights to refuse and discontinue participating to the participants; before asking for their consent to participate in the study. Those who agree to participate in the study were asked to sign a form on the protection of human subjects (Appendix G).

5. The participants were asked to answer the following questionnaires in the following order: 1) the Demographic Data Form; 2) the Knowledge of Hypertension Scale; 3) the Provider-patient Communication Scale; 4) the Hypertensive Social Support Scale; 5) the Hypertensive Health Belief Scale; 6) the Hypertensive Self-efficacy Scale; and 7) the Hypertensive Adherence to Therapeutic Regimens Scale. They responded to all questionnaires while waiting for their medicines. The Demographic Data Form was recorded by the researcher. The rest of questionnaires were recorded by literate participants. Upon completion, they returned the questionnaires directly to the researcher. The researcher rechecked all the questionnaires and thanked the participants for their participation.

Data Analysis Procedures

The overall level of significance was set at an alpha of .05. The details of data analysis are described as follows:

1. The demographic data of the samples were analyzed by descriptive statistics including frequency, percentage, mean and standard deviation.

2. All variables were described by descriptive statistics. Mean and standard deviation were computed. The percentage of each category was shown.

3. When using structural equation modeling (SEM) analysis, the assumption of multivariate analyses were applied, these include normality, linearity, and absence of multicollineritity.

3.1 *Testing of normality*. All variables studied were tested for normal distribution. Skewness and kurtosis were used to assess normality of variables which are interval and ratio scale. The values of skewness and kurtosis are zero when a distribution is normal. When the variables were nominal and ordinal scale, a histrogram was used to test for distribution. If nonnormality was found, transformation of variables was considered. For a flat distribution, the transformation is the inverse. Negatively skewed distributions could be transformed by a square root transformation, and logarithms for positive skewness (Hair, Anderson, Tatham, & Black, 1998; Tabachnick & Fidell, 2007).

3.2 *Testing of linearity between the variables.* Linearity is an assumption that is a straight-line relationship between a predictor and criteria variables (Tabachnick & Fidell, 2007). Linearity between two variables was assessed by inspection of bivariate scatterplots or statistical test by ANOVA. The scatterplots

is oval-shaped if both variables are normally distributed and linearly related (Tabachnick & Fidell, 2007). Transforming data in one or both variables is the method which will be used to achieve linearity if a nonlinearity relationship is uncovered. An alternative to data transformation is the creation of new variables to represent the nonlinear portion of the relationship (Hair et al., 1998).

3.3 *Testing of multicollinearity between the predictor variables.* Multicollinearity means high correlations between predictor variables. When predictor variables are multicollinear, they contain redundant information. If a bivariate correlation is too high, it presents in a correlation matrix as a correlation above .90. There are three statistics to examine the multicollinearity. First, if the square multiple correlations (R^2) between each variables and all the rest are greater than .90 this suggests extreme multicollinearity. Second, the tolerance (1- R^2) values less than 0.10 may indicate a mulitcollinearity. Third, if the variance inflation factor [VIF = 1 ÷ (1- R^2)] is more than 10 it may be redundant with others (Kline, 2011). Two basic ways to deal with mulitcollinearity are to eliminate variables or combine redundant ones into composite variables (Kline, 2011).

4. Structural equation modeling (SEM) was conducted to statistically test a priori hypothesized model against empirical data using the student version of the LISREL 8.7. The advantage of the SEM technique allows the researcher to estimate the direct and indirect relationships between one or more independent variables and one or more dependent variables simultaneously (Kline, 2011). Therefore, LISREL was used to test the structural model and the causal model based on the covariance matrix occurring among the variables. After all assumptions were met, the analysis of

SEM preceded approach. The methods examined in the hypothesized model were described as follows:

Firstly, the assessment of overall fit of the model is the method to evaluate the structural model. Overall model fit indicates the fit of the structural model to the data. A model is 'good' if there is a fit between the sample covariance matrix and the estimated population covariance matrix. Chi-square (χ^2) is a basic statistic to measure goodness-of-fit available in SEM. The statistical significance of χ^2 indicates the statistical difference of the actual and predicted input matrixes. A result of a nonsignificant difference level of .05 is recommended as the minimum acceptable value (Hair et al., 1998; Kline, 2011). However, χ^2 is very sensitive to sample size, if the sample size is large, especially for cases in which the sample size exceeds 200 respondents, the index may be interpreted as significance (Hair et al., 1998). To reduce the sensitivity of the χ^2 statistic to sample size, the norm Chi-square which is the ratio of χ^2 divided by its degree of freedom (χ^2/df) was used to indicate the model fit. The χ^2/df ratio less than 3 is acceptable (Hair et al., 1998; Kline, 2011).

The Goodness-of-fit indices (GFI) are the square residual of prediction and actual data comparison reflecting the overall degree of fit. Its value ranges from 0 (poor fit) to 1 (perfect fit). A value of GFI above 0.90 is recommended (Hair et al., 1998; Kline, 2011). The Adjusted goodness-of-fit indices (AGFI) are an extension of GFI. It is adjusted by the ratio of degree of freedom for the proposed model to the degree of freedom for the null model. A value over 0.90 is recommended (Hair et al., 1998; Kline, 2011). The GFI and AGFI are more standardized and may be less sensitive to sample size than χ^2 (Kline, 2011).

The root mean square error of approximation (RMSEA) is the discrepancy, which is expressed per degree of freedom in terms of the population and a measure that attempts to correct for tendency of the Chi-square statistic to reject any specified model with a sufficiently large sample (Hair et al., 1998). A value range from .05 to .08 is acceptable. A value less than .05 indicates a good fit, and values as high as .08 show reasonable errors of approximation in the population. A model that has the smallest RMSEA value, not only represents model fit, but also indicates model parsimonious (Hair et al., 1998).

Lastly, the root mean square residual (RMR) is a measure of the mean absolute covariance residual which its value closer to zero is indicated perfect model fit, and increasingly higher values indicates worse fit. The standardized root mean square residual (SRMR) is a measure of the mean absolute correlation residual, the overall difference between the observed and predicted correlations. The value SRMR of $\leq .05$ is acceptable fit (Kline, 2011).

Secondly, assessment of the actual size of parameter is performed. The standardized path coefficients (β) which indicate direct effect size are shown by beta weights in regression. The significance of each pathway depends on the value of *T-value* if *T-value* of ≥ 1.96 indicated that the standardized path coefficients had statistic significance at $p < .05$ and *T-value* of ≥ 2.58 as $p > .01$. The indirect effects of the independent variables for each pathway model are also estimated by using the standardized path coefficient (β). A large standardized path coefficient that is highly significant validates the causal pathway (Burns & Grove, 2005). Further, in each significant pathway analysis, there are three types of structural effects: direct, indirect,

and total effects. Finally, the overall coefficient of determination (R^2) is calculated and it provides a relative measure of fit for each structural equation (Hair et al., 1998).

5. Model modification could be applied when the model does not fit the data in the purposed model. It should be noted that model modification is concerned not only with the statistical values but also is relevant to substantive knowledge and literature support (Hair et al., 1998). Therefore, this step is performed based on both statistical and knowledge evidence. This step could be respecified as the final model by eliminating non-significant paths, adding paths or parameters with a large modification index which can be interpreted substantively. The modification index approximates the amount by which the model's overall χ^2 would decrease if a particular parameter is freely estimated. The greater the value of modification index (> 3.84), the more the overall fit of the model will improve if that parameter is added to the model (Hair et al., 1998; Kline, 2011). Then the step for assessing the structural model will be repeated.