CHAPTER 3

Methodology

Research Design

A descriptive, cross-sectional, predictive correlation design was used to examine predicting factors and test a causal correlation between selected variables including physical function, cognitive function, social support from family, knowledge of hypertension, provider-patient communication, perceived benefits, perceived susceptibility, perceived severity, perceived barriers, and perceived self-efficacy to adherence and adherence to therapeutic regimens among older adults with hypertension. These variables synthesized from the relevant literature review were selected because they could be modified by the nursing role. Self-report questionnaires were used to draw together the quantitative data and structural equation modeling (SEM) was used to analyze the hypothesized causal model.

Population and Sample

Population

The target population were older persons aged 60 years and over, diagnosed with hypertension for at least 6 months and had follow-up at hypertension clinic in any of five community hospitals in Phayao province, northern Thailand. Phayao province was chosen because the number of older adults with hypertension in this province was continuously increasing compared with neighbors. Furthermore, this age group was nearly the same as that reported in the 4th Thai National Health Examination Survey.

Sample and Sample Size

The samples of this study were randomly selected from the older hypertensive patients who attended one of five community hypertension clinics in Phayao province. The inclusion criteria that were used to select participants of this study included: (1) age 60 years or over (2) having been diagnosed with hypertension for at least 6 months (3) taking at least one type of antihypertensive drug 4) having no symptoms that could interfere with a patient's ability to respond to the self-report questionnaires (5) being able to understand the Thai language and (6) willing to participate in the study. The sample size in the hypothesized model for this study was calculated, based on the guideline of calculating the sample size for basic multiple regression (Polit & Beck, 2008). The estimation of sample size was estimated by using power analysis, effect size and 15 observed predictor variables from the hypothesized model that could be divided into two steps which were described as follows:

1. Calculating the estimated population effect size (γ) using the following formula (Polit & Beck, 2008).

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

According to the range of the value of R2 used to estimate the population effect size, it could be divided into three levels including the value of R^2 = .02-.12 (small), R^2 = .13-.29 (moderate), and $R^2 = \geq .30$ (large) (Polit & Beck, 2008). This study used the small level of value of R^2 = 0.06 to estimate population effect size. The result of the estimated population effect size in this study after substituting R^2 = 0.06 in to the formula was .075. (γ = 0.075)

2. Calculating the sample size of pathway analysis for the hypothesized model was computed with the formula (Polit & Beck, 2008) as follows:

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

where N = estimated number of subjects needed

L = tabled value for the desired a and power

K = number of predictors (observed variable for each factor)

γ = estimated effect size

The power was defined as the capacity of the study to detect differences or relationships that actually exist in the population. The minimum acceptable power for each study was .80 (Burns & Glove, 2005). Also, the power analysis table for multiple regression that could determine the power value ranged from .50 to .90 (Polit & Beck, 2008). Therefore, determining the acceptable power for this study and the desirable function of the significance level (α) for controlling type I errors were .80 and .05 respectively. There were 15 observed variables of predicting factors from the hypothesized causal model, including 4 observed variables from health belief (perceived benefits, perceived susceptibility, perceived severity, and perceived barriers) and social support from family (emotional, appraisal, informational and instrumental support), 3 observed variables from provider-patient communication (clarity, responsiveness, explanation), and one observed variable from cognitive function, physical function, knowledge of hypertension, and perceived-self efficacy to adherence. The power analysis table for multiple regression using the value of L for a = .05, power = .80 and predicted variables were 18.81 (Polit & Beck, 2008). Substituting these values into the formula and the estimated sample size for this study was 310. To offset the dropout rate, 10% of estimated sample size was added. Thus the minimum estimated sample size of this study were 341.

Sampling Method

Simple random sampling method was used to obtain the required sample who had met the inclusion criteria from the name of registered hypertensive elderly patients who were listed in the database of each hospital in five community hospitals. With 341 cases of sample size for this study, they were randomly selected according to proportion of the number of the registered hypertensive elderly patients in each hospital. The number of sample in the study in each community hospital are described in Table 3-1 as follows:

Table 3-1

The Number of Sample in the Study in Each Community Hospital

Community hospital	Target population	The number of sample
Dok Kham Tai	2,716	103
Pong	1,844	70
Chun	1,617	61
Mae Chai	1,467	56
Chiang Muan	1,357	51
Total	9,001	341

This study will collect data in the Phayao province, at five hypertension clinics in five community hospitals. These hypertension clinics provide services for hypertensive patients who are recommended for follow-up visits and the new registered patients every 1-2 days per week from 8.00-12.00 am. or 08.00-16.00 pm. In general community hospitals, there are general physicians usually providing their treatment for patients with complications or uncontrolled blood pressure, while, patients who can control their blood pressure, or with no complications, are mainly provided for by the practitioner nurses. Providing health care services and giving health education for hypertensive patients is a major role of the staff nurses in all hypertension clinics.

Research Instruments

Nine instruments were used to collect data in this study and were presented as follows:

The Demographic Data Form

It was developed by Pinprapapan (2013). This form was used to obtain the personal characteristics of participants and social background, including gender, age, employment, marital status, educational level, personal income, 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 of antihypertensive medication, number of medicines taken per day (tablets), number of times of medication used per day, the interval of follow-up visits and blood pressure level.

The Chula Mental Test (CMT)

This inventory developed by Jitapunkul et al. (1996), contains 13 items and the domains of this instrument consist of remote memory, orientation, attention, language, abstract thinking, judgment, and general knowledge. The response to each item is a dichotomous scale coded 1 (correct) and 0 (incorrect). The total scores ranged from 0-19. The interpretation of scores is shown in four categories including normal cognitive function (scores 15-19), mild cognitive impairment (scores 10-14), moderate cognitive impairment (scores 5-9), and severe cognitive impairment (scores 0-4) (Jitapulkul et al., 1996). The reliability of this instrument tested by test re-test was r = 1.00; $p < .01$.

The Chula Activity of Daily Living Index (CAI)

This inventory was developed primarily by Jitapunkul et al. (1994) in Thailand. It is used to measure physical function of Thai older people living in several settings in both hospitals and the community. This scale consists of five items for self rating of the complexity of activities daily life. It was unequal for each item, having either a two point or four point scale. Walking outdoors, having only one item with four responses on a scale (0-3 scale), was coded with the score of incapable of walking (0), using a wheel chair or partial assistance requiring at least two persons (1), walking with help from another person (2), and walking independently by oneself (3). The items, cooking and transportation have three response scales including inability for any activities (0), partial assistance from another person (1), and independently doing by oneself (2). The others, consisting of money exchange and heavy house work, are dichotomous scales with responses for not doing (0), and independent or doing by oneself (1). The total possible scores for this inventory range from 0 to 9 and interpreted by the range of total scores, the higher the total score, the greater the physical function and the lower the total score, the lower the physical function. The test-retest reliability for this scale was r = 1.000; $p < .01$.

The Hypertensive Social Support Scale (HSSS)

This instrument was developed by Pinprapapan (2013) which was based on House (1981). It was used to measure the level of perceived support for performing recommended behaviors to meet the optimal blood pressure control. This scale consists of 20 items with four types of social support including emotional (6 items), informational (4 items), instrumentional (5 items), and appraisal support (5 items) and the response to each items uses a 4- point rating scale ranging from 1 (not true) to 4 (strongly true). The total scores range from 20 (the lowest) to 80 (the highest). Higher scores indicate better social support. The internal consistency reliability was tested in 15 subjects who met the same inclusion criteria for this study and the Cronbach's alpha coefficient was .80. The final test for the reliability of the *HSSS* which computed for the 341 sample of this study was 0.894.

The Hypertension Knowledge-Level Scale (HK-LS)

This scale was developed by Erkoc et al. (2012) and was first used to measure hypertension knowledge among Turkish adults. This scale was firstly translated into Thai language by the researcher and advisors and it was led to back translation of the Thai version to English by a Thai bilingual expert in order to enhance equivalence (Appendix B). This scale is a self-report questionnaire consisting of 22 items with sub-dimensions. The items of sub-dimension encompasses the definition of hypertension (2 items), medical treatment (4 items), drug compliance (4 items), lifestyle (5 items), diet (2 items), and complications (5 items). The responses are all dichotomous including correct (to be worth 1 point), and incorrect (to be worth 0 point). The scores have a range from 0 to 22. Total score of 18 and above is considered adequate level of knowledge. The Kuder-Richardson 20 (KR-20) was used to test the internal consistency reliability in 15 subjects who met the same inclusion criteria of the study and reported to be .799. In addition, the final test of the *HK-LS* which computed for the 341 sample of this study was 0.551. This value of reliability was lower than that of preliminary study, because it may be that the data are not normally distributed.

The Provider-Patient Communication Scale (PCS)

This scale was developed by Pinprapapan (2013) to measure the patients, perception of provider's communication regarding talking clearly, explaining medical care and responding to patients' concerns. It consists of 9 items and is categorized into 3 domains including general clarity (2 items), explanation of hypertension and medical care (4 items) and carefully listening to and responsiveness to patients' problem and concern (3 items). The response to each item is on a 4-point Likert scale ranging from 1 (never) to 4 (always) and 1= always to 4 = never for negative items. The total scores have a range from 9 to 36 and the higher scores indicate better communication between patients and health care providers. The internal consistency reliability was applied to test in 15 subjects who met the same inclusion criteria of the study and the Cronbach's alpha coefficient was .818. In addition, the final test for the *PCS* which computed for the 341 sample of this study was 0.475. The value of reliability was lower than that of preliminary study, because it may be that the data were not normally distributed.

The Health Belief for Hypertensive Patient Scale (HBHS)

This inventory, developed by Pinprapapan (2013), based on Becker's Health Belief Model, is used to measure perceived susceptibility to induce complications, perceived severity of complications, perceived benefits of performing antihypertensive drugs taking and lifestyle modification and perceived barriers to perform adherence to antihypertensive drug taking and lifestyle modification for hypertensive patients. It consists of 26 items and the response to each item is on a 4-point rating scale. There are four parts for measuring health belief containing 7 items of perceived susceptibility, 6 items of perceived severity, 6 items of perceived benefits and 7 items of perceived barriers. The coding of positive items is on a 4 point rating from 1 (not agree) to 4 (mostly agree), while the items of perceived barriers with negative meaning are coded ranging from 4 (not agree) to 1 (most agree). The possible scores range from 26-104. The higher the score refers the more appropriate the health belief with the result that the persons with hypertension had a higher level of perceived benefits, perceived susceptibility, and perceived severity and a lower level of perceived barriers. The internal consistency reliability was applied to test in 15 subjects who met the same inclusion criteria of the study and the Cronbach's alpha coefficient was .847. In addition, the final test for four scales of HBHS which computed for the 341 sample of this study including perceived barriers, perceived benefits, perceived susceptibility, and perceived severity was 0.77, 0.58, 0.73 and 0.89 respectively.

The Hypertensive Self-efficacy Scale (HSS)

This scale, developed by Pinprapapan (2013) was used to measure perception of the hypertensive patients on their confidence to perform adherence to therapeutic regimens. The scale contains 26 items which consist of 6 items for the taking of antihypertensive medication, 4 items for dietary modification, 2 items for weight control, 6 items for physical exercise, 4 items for avoiding risk factors, 2 items for stress control, and 2 items for follow-up visits. The response to items is on a 4 point Likert scale and the response for each item ranges from 1 (least confidence) to 4 (most confidence). The total ranges from 26 (the lowest) to 104 (the highest). The higher level score indicates a higher level of self-efficacy to adherence. The internal consistency reliability was applied to test in 15 subjects who met the same inclusion criteria of the study and the Cronbach's alpha coefficient was .808. Moreover, the final test for the reliability of the *HSS* which computed for the 341 sample of this study was 0.837.

The Hypertensive Adherence to Therapeutic Regimens Scale (HATRS)

This scale, modified by Pinprapapan (2013) was used to measure both adherence to medication and lifestyle modification in hypertensive patients. This scale is comprised of 29 items with four attributes, including 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). Each item will have a response on a 4 point-Likert scale ranging from 1 (not true) to 4 (strongly true). The total score range is from 29-116. A higher score level means a higher level of adherence to therapeutic regimens. The internal consistency reliability was applied to test in 15 subjects who met the same inclusion criteria of the study and the Cronbach's alpha coefficient was .80. The final test for the reliability of the *HATRS* which computed for the 341 sample of this study was 0.835.

Protection of Human Rights

The processes of this study followed ethical principles for human research study. Before collecting data, this approval proposal and instruments were approved by the Research Ethics Committee of Faculty of Nursing, Chiang Mai University (Appendex D). Moreover, permission letters from the Public Health Office of Phayao province and the directors of the selected community hospitals were obtained prior to collecting data. Data collection started after getting permission from the Public Health Office of Phayao province and the directors of the selected community hospitals. All eligible subjects were asked to participate voluntarily for the process of sample recruitment for this study. They were given the significant descriptions related to the ethical principles. These details of the explanations for this study were comprised of the purpose, methods, the duration of time required to complete the questionnaires, the potential risk, and benefits of participations. Also, the confidentiality of the subjects was protected before being recruited into this study. Before the subjects sign consent form, they were informed of their rights, including the right to refuse, to ask for clarification, or to withdraw from this study anytime and without having any effects on their treatments or their services. After signing the consent form, they were asked to answer the questionnaires at a private place of in the hospital close to the hypertension clinic without interruption from any people. Recognizing, the confidentiality and anonymity of the subjects' data were important tasks. All subjects were given a code number to replace their name, the given answer of questionnaires, and reported finding as a whole. Also, these documents consisting of given information by subjects were concealed the identification and were kept in a locked cabinet which only the researcher could access. Lastly, when they agreed with the described information to participate in this study, they were asked to sign the informed consent form.

Data Collection Procedures

The processes of collecting data were described as follows:

1. The permission letters for data collection from Faculty of Nursing, Chiang Mai University were sent to the heads of the Provincial Public Health Office in Phayao province, and the directors of selected five community hospitals. After, permission was approved prior to collection data, the researcher visited each hospital and reported the important information such as the purpose of the study and its benefits to the director of each hospital, the head nurse, and their health care team who were working in hypertension clinic.

2. Before inviting subjects to participate in this project, the researcher reviewed the medical record of each hypertensive older patient the day before for follow-up visits of registered patient's data, in order to select potential subjects who met the inclusion criteria. Then, the researcher recorded the list of eligible subjects and selected randomly according to proportion of the number of the registered hypertensive elderly patients in each hospital.

3. Before asking subjects to participate in this study, the researcher clearly described the purpose, the benefits, and the subject's rights to refuse or discontinue participating for this study without any effects on them based on the principle human rights protection. When those subjects agreed to participate in the study, they were asked to sign a consent form for protection of human subjects.

4. The questionnaires were answered by the participants in the private zone of the hypertension clinic while waiting for their physicians. In addition, if some participants required answering privacy in answering the questionnaires, the researcher would collect data at their home.

5. In case participants were unable to read and answer questionnaires, the researcher assisted them by reading the questions and writing the answers without explanation.

6. The questionnaires were administered to the participants in consideration of the ease of use. During responding to questionnaires, the participants were advised to answer questionnaires in order of the ease of use. To begin a first set of questionnaires including (1) The Demographic Data Form (2) the Chula Activity of Daily Living Index

(CAI) and (3) the Chula Mental Test (CMT) were given to participants. When these questionnaires were completed, the participants were allowed to take a break for approximately 10 minutes. The second set of questionnaires including (1) the Hypertension Knowledge-Level Scale instrument (HK-LS) (2) the Provider-Patient Communication Scale (PCS) and (3) the Health Belief for Hypertensive Patient Scale (HBHS) were subsequently administered. They were then allowed to take a break of around 15 minutes. The last set of questionnaires including (1) the Hypertensive Social Support Scale (HSSS) (2) the Hypertensive Self-efficacy Scale (HSS) and (3) the Hypertensive Adherence to Therapeutic Regimens Scale (HATRS) were finally completed. The total time spent to complete all questionnaires approximately ranged between 60 and 80 minutes.

7. The researcher rechecked all the questionnaires directly after receiving them from the participants and thanked all participants for their willing participation.

Data Analysis Procedures

The demographic characteristics of the sample were described by the descriptive statistics. Pearson's product moment correlation was used to analyze the bivariate relationship among all study variables and their respective components. Also, a structural equation modeling was tested by using the Generalized Least Squares (GLS) technique in the LISERL 8.80 (Student edition) program. The processes of data analysis will be explained as follows:

1. The descriptive data regarding the personal information of samples were analyzed using descriptive statistics including frequency, percentage, range, mean, and standard deviation. Also, the entire variables were analyzed using mean and standard deviation. The data were shown the percentage of each category.

2. The data were analyzed using the structural equation modeling (SEM) to confirm the hypothesized causal model of adherence to therapeutic regimens among the elderly with hypertension. However, when using SEM, it is necessary to test the assumption of multivariate before its analysis. This study tested with levels of alpha significance of .05. The assumptions were tested, including multivariate normality, the absence of outliers, linearity, homoscedasticity, and the absence of multicollinearity. Testing the assumptions were described as follows:

2.1 *Testing of normality.* All variables in this study were tested for normal distribution with univariate statistics. In general, if all variables are interval and ratio scale, skewness and kurtosis are used to test normality of variables. when the assumption with normal distribution of all variables, the results with normal distribution have values of skewness and kurtosis of zero. Whereas, histrogram is used to test the distribution in the norminal and ordinal scale of the variables. When the results were not a normal distribution, transformation of the variable was considered using two main techniques, including logarithms for positive skewness and a square root transformation for negative skewness. It could also be noted that the greater the sample size, the more effective the assumption of normal distribution (Hair, Black, Babin, Anderson, & Tatham, 2006; Kline, 2011; Tabachnick & Fidell, 2007).

2.2 *Testing of linearity between the variables.* In general linearity is the pattern of relationships between each pair variables such as dependent variables and one or more independent variables in the path model. Also it could show an adequate level of their correlation coefficient. Linearity is analyzed by two residual plots including the bivariate scatterplots and normal P-P plots which show a straight line in the graph, meaning it meets the assumption of linearity. It is also tested by ANOVA. If the relationship is nonlinear, the data will be transformed for achieving linearity (Hair et al., 2006; Tabachnick & Fidell, 2007).

2.3 *Testing of multicollinearity between the predictor variables.* Multicolinearity refers to the high correlation among the independent variables leading to a redundancy of information (Hair et al., 2006; Kline, 2011). If this correlation is too high, it will decrease the ability of independent variables to predict the dependent variables. Hence, multicolinearity may affect the predictive ability of describing regression model and the estimate of the regression coefficients and the statistical significance tests (Hair et al., 2006). Identifying the multicolinearity is an examination of the correlation matrix for the independent variables. The general result of high correlations is .90 and higher (Hair et al., 2006). To examine the multicolinearity, three statistics can be used for testing, including a squared multiple correlation (R^2_{smc}), tolerance, and variance inflation factor (VIF). If calculating the squared multiple correlation (R^2_{smc}) between each independent variable and all the rest are more than 0.90, it will indicate mulitcolinearity. Tolerance which equals 1- R^2_{smc} is another method to examine the mulitcolinearity. If this value is less than 0.10, it will indicate mulitcolinearity. Finally, if the variance inflation factor (VIF) which equals $1/(1- R^2_{smc})$ is more than 10, it may be interpreted as having a redundancy of variables (Kline, 2011). Dealing with the multicolinearity problems such as eliminating variables, or combining the redundant ones into composite variables are acceptable methods in this occurrence (Kline, 2011).

3. Structural equation modeling (SEM) was used to analyze the hypothesized model against the empirical data by using the student version of the LISREL 8.80. SEM is the best multivariate procedure for examining both the construct validity and the theoretical relationships among a set of concepts (Hair et al., 2006). It is more helpful for accurately accessing the strength of the relationship between factors due to having the characteristic of correcting the relationship for measurement error (Hair et al., 2006). Also, to estimate simultaneously the direct and indirect relationships between one or more independent variables and one or more dependent variables is the significant benefit of the SEM technique (Kline, 2011). Thus, this study used the SEM to test the structural model and the causal model based on the covariance matrix occurring among the variables. To analyze data with SEM by the LISREL program, the two significant methods examined in the hypothesized model were described as follows:

Firstly, the assessment of overall fit of the model is examined by assessing model fit as a whole in order to confirm the fit of model between structural model and data. There are four major values generally used to recommend the fit of model in SEM. The first one is Chi-square (χ^2) which is the traditional statistic used for the measurement of fit of the model in SEM. It is basically used to indicate the differences between the observed and estimated covariance matrix in SEM. The recommendation for the goodness of fit of the model (no differences between the observed and estimated covariance matrix) examined by Chi-square value (χ^2) is a non-significant difference at level .05. Thus, it could be concluded that the lower χ^2 value, the lower the difference of covariance matrices (Hair et al., 2006). Moreover, concerning the norm Chi-square which is the ratio of χ^2 divided by its degree of freedom (χ^2/df) is the main point to confirm the model fit. If this value is less than 3, it indicates the model fit with the empirical data (Hair et al., 2006; Kline, 2011). The second value is the goodness-of-fit index (GFI) which is a robust statistic for small samples sizes. It is used to recommend the level of the fit with the model ranging from 0 (poor fit) to 1 (perfect fit). Commonly, the value of GFI for an acceptable fit is more than 0.90, whereas others agree on a value of at least 0.95 (Hair et al., 2006). Another value is the Adjust goodness-of-fit indices (AGIF) which is derived from GFI. The recommendation for the fit of the model using the AGFI value is over 0.90 (Hair, Anderson, Tatham, & Black, 1998; Polit & Beck, 2008). The third value is the Root Mean Square Error of Approximation (RMSEA). It is a suitable value representing how well a model fits the population and is also widely used in a confirmatory or competing model strategy when the sample size is larger. The enable value of RMSEA used in SEM is reported between 0.03 and 0.08, with 95% confidence (Hair et al., 2006). However, the acceptable value indicating a good model fits is less than 0.05 (Hair et al., 1998). Lastly, the root mean square residual (RMR) is a measure of the mean absolute covariance residual. When the RMR value is close to zero, it indicates a perfect model. Moreover, the standardized root mean square residual (SRMR) is one of the significant values that is considered when testing model fit. It is a measure of the mean absolute correlation residual and the overall difference between the observed and predicted correlations. The acceptable value of the SRMR resulting the model fit is less than or equal 0.05 (Kline, 2011).

Secondly, to assess the actual size of the parameter, the first step to assess SEM is determining the parameters which represent the structural relationship between constructs. The correlation of constructs is divided into two types. The first type is the relationship of exogenous constructs to endogenous constructs represented by the gamma matrix (γ). The other type is the relationship of endogenous constructs to endogenous constructs, referred by the symbol (β), which is an important validation of the causal pathway. This result of the relationship is estimated by β coefficients, or the standardized coefficient, which shows both the direct and indirect effects of the independent variable for each pathway model (Hair et al., 2006). The significance of each pathway is determined by the value of T-value. The statistic significance of standardized path coefficients (β) is indicated by two values, including *T-value* of ≥ 1.96 as $p > .05$ and *T-value* of ≥ 2.58 as $p > .01$. A highly significant validation of the causal pathway is indicated by a large β coefficient (Burns & Gloves, 2005). In addition, the pathway model is portrayed with three types of structural effects, including direct, indirect and total effects (Hair et al., 2006). Also, a relative measure of fit for each structural equation is provided by the overall coefficient of determination (R^2) (Hair et al., 1998).

4. Model modification is an important method to apply for modifying the model if the proposed model does not fit with the data. When the findings showing the statistical values of the model do not fit with the empirical data, they should be modified until the findings showing a rationally good overall model fit. In general, the step for modifying the model may be achieved by cutting of the nonsignificant paths or adding paths or parameters with a large modification index (Hair et al., 2006). However, considering modifying the model, it should be concerned simultaneously with the literature review supporting the hypothesized causal model and the statistical value (Hair et al., 1998; Hair et al., 2010).