

CHAPTER 3

RESEARCH METHODOLOGY

This chapter presents materials and methods organized in the topics: research design, study population and subjects, then the research intervention, instruments, data collection, and statistical analysis of the data.

Design of the Study

This was a quasi-experimental study with a pretest - posttest control group design. It studied the effects of an eight-week Yoga program, consisting of yoga practice and health informational support based on yogic principles, on stress and blood pressure in persons with hypertension. The experimental group participated in the Yoga program and routine care, while the control group was given routine care only by Songkhla hospital's health personnel, as shown in Figure 4.

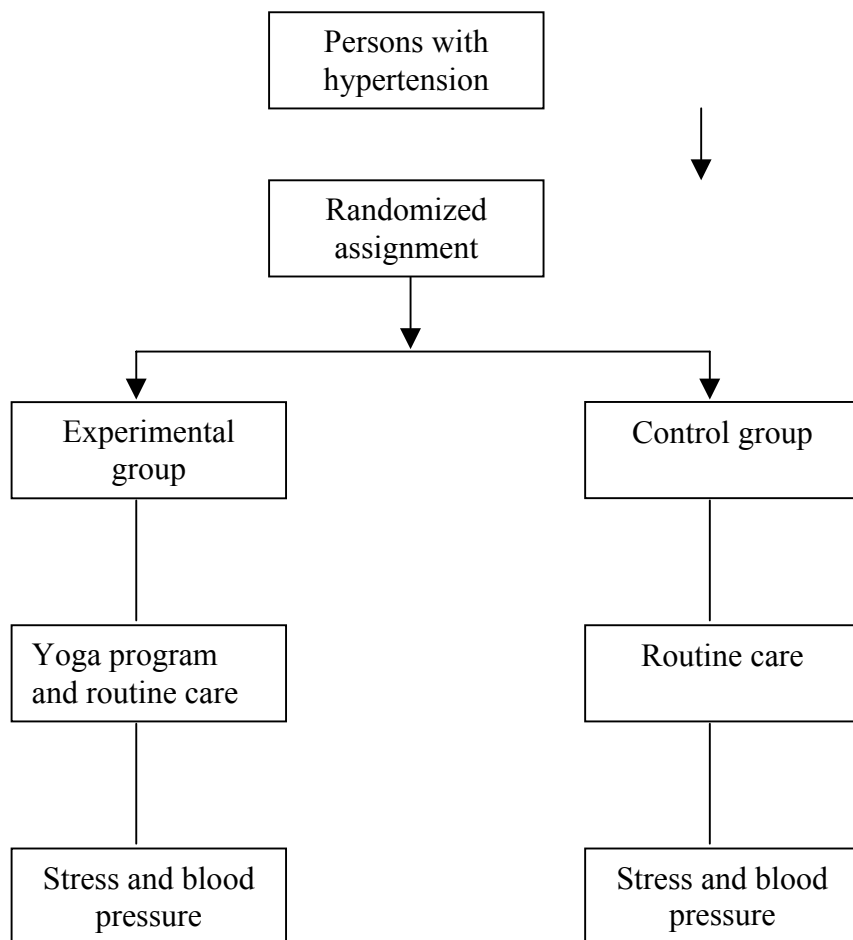


Figure 4: Design of the study

Population and Samples

The target population of this study was persons diagnosed by a doctor as having hypertension or someone presenting with a blood pressure greater than 140/90 mmHg. The number of subjects required was derived through power analysis according to Polit and Hungler (1999) at significance level (α) of .05, power of statistic test ($1-\beta$) of 0.80, and effect size of 0.8. The sample required was 25 subjects. This sample size had been confirmed by previous research studies on yoga practice in Thailand (Sonchan, 1998) and other countries (Bera, Gore, & Oak, 1998; Malathi, & Damodaran, 1999; Muragasan, Govindarajulu, & Bera, 2000; Schmidt,

Wijga, Vonzur Muhlen, Brabant, & Wagner, 1997; Selvamurthy et al., 1998). The sample size they used ranged from 6 to 38. A sample group as small as 10, studied by Selvamurthy and colleagues (1998), showed a statistically significant reduction of blood pressure in persons with essential hypertension. Bera, Gore, and Oak studied (1998) a sample 25, and showed a statistically significant reduction of stress among medical students. Although twenty-five subjects in each group were required, the sample size was extended to twenty-seven subjects in each group to allow for dropouts. The persons with hypertension who met the inclusion criteria and agreed to practise yoga according to the program were invited to join the study. Purposive sampling was used to recruit subjects during July –November 2003 from the hospital mobile clinic for health promotion program, and the referral system of the primary care units in the province. Eighty- seven subjects entered the run in phase but only 61 met the criteria and quality for randomization at the pretest. Any subjects, who took antihypertensive medication at any stage of the study and/or did not practice yoga according to the program, three times a week for eight consecutive weeks, were excluded from the study. So, at the completion of the study the number of subjects for each group was twenty-seven (Figure 5).

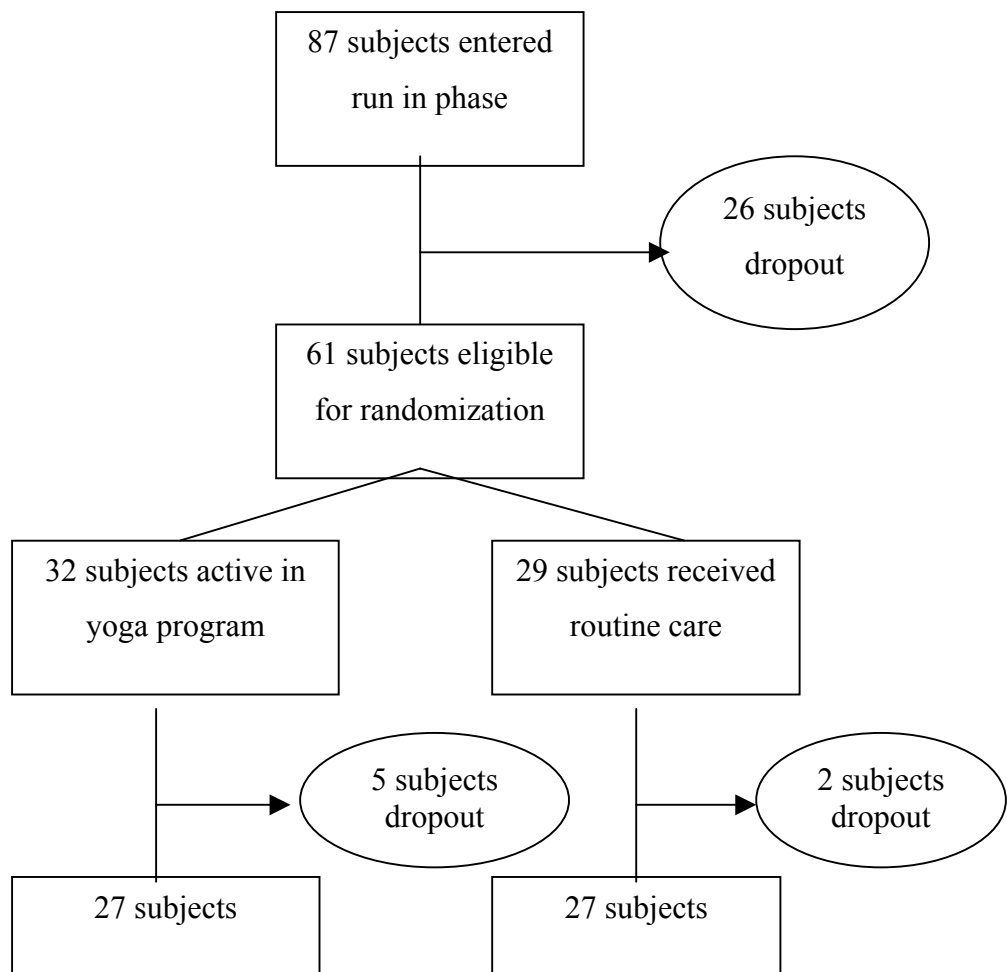


Figure 5: Population and sampling of study

In order to assure homogeneity between the experimental and control groups, subjects were matched by using the minimized randomization version 2.01 of Zeller (1997) to control variables affecting stress and blood pressure. These variables were age, gender, level of education, smoking, alcohol use, and exercise.

The inclusion criteria for subjects were:

1. Being diagnosed with essential hypertension or having mild or moderate hypertension classified by the Joint National Committee (1997) with no use of antihypertensive medication during the period of yoga practice. You can't know that at the time of recruitment and what about before recruitment
2. Having a mean score of stress of more than 1 measured by the Stress Assessment Questionnaire
3. Willing to participate in this study for at least 8 weeks consecutively
4. Able to communicate in Thai
5. No use of antidepressant medication during the entire period of the study.
6. No physical conditions that might be affected by yoga practice such as severe joint pain, or/and other severe diseases (heart disease, CVA, renal failure, and cancer).

Instruments

The instruments in this study were classified into two categories as follows:

1. Instruments and data collection consisting of three data collection forms: Demographic Data Form, Stress Assessment Questionnaire, and Blood Pressure, Weight and Yoga practice Record Form
 - 1.1 Digital blood pressure manometer, Model ALPK2 DS125d
 - 1.2 Weight scale for measuring body weight
 - 1.3 The demographic data consisted of age, gender, marital status, education level, occupation, religion, income, and history of smoking, alcohol use, exercise, fat eating behavior, salt eating behavior and history of hypertension.

1.4 The Stress Assessment Questionnaire was modified from Stress of Symptom Inventory (SOS) proposed by Thammakoon with permission. The original questionnaire was published in the Cornell Medical Index, which had been developed by Leckie and Thompson at the Department of Psychosocial Nursing, University of Washington. It had been translated into Thai by Majorie A. Muecke. This questionnaire consists of 107 items. Thammakoon had later modified the questionnaire and reduced the number of items to 75 to be used for stress assessment in her study (Thammakoon, 1989). The researcher further modified Thammakoon's version to 64 items and named it the Stress Assessment Questionnaire (SAQ) in order to better fit with people with hypertension. The SAQ uses close-ended questions to be answered on a 5-point scale: 1 for never to 5 for very frequently. The level of scale range was illustrated as follows:

- 1 refers to never responding to the experience
- 2 refers to infrequently responding to the experience
- 3 refers to sometimes responding to the experience
- 4 refers to often responding to the experience
- 5 refers to very frequently responding to the experience

The total stress score was obtained using the sum of the experiences in one month. The total possible score was 64-320 and the mean score was reduced to 1-5. The stress level was classified into five levels by using the mean score of stress. The higher scores indicating higher stress whereas low scores refer to low stress (Thummakoon, 1989).

- | | |
|------------|---------------------------------|
| 1.01-1.49 | refers to extremely mild stress |
| 1.50- 2.49 | refers to mild stress |
| 2.50- 3.49 | refers to moderate stress |

3.50- 4.49 refers to severe stress

4.50 -5.00 refers to very severe stress

1.5 The Yoga Practice Record Form consists of information about yoga practice, height, body weight, respiratory rate, heart rate, and blood pressure. This form, consisting of two parts, was completed by the researcher and the research assistant.

Part 1 A form was used to document the frequency of yoga practice that the subjects performed in the experimental group. Subjects who practiced yoga less than three times a week were excluded. Other risk factors such as stress crisis, smoking, alcohol use, inactivity, and salt eating behaviors were documented in both groups.

Part 2 A form was used to document the blood pressure, heart rate, respiratory rate, height, and body weight. It was recorded in the experimental group and at the end of every two weeks for the control group.

2. Instruments for the Yoga program consisted of a booklet for yoga practice with information about hypertension and stress management based on yogic principles, and a cassette tape of yoga guidance.

The researcher developed the Yoga program based on yogic principles (Anandamitra, 2000; Kulkarni, 2001; Nagarathna, Nagendra, Monro, 1995; Central Council for Research in Yoga & Naturopathy, 1999; Yogendra & Desai, 2001) and engaged in yoga training.

2.1 The booklet contained information about hypertension and stress management based on yogic principles and described yoga practice including asana, pranayama and deep relaxation (illustrated in Appendix E). It also covers the benefits to be gained from practice, how to prepare to practice and the principles of practice with a picture of each posture.

2.2 The Yoga cassette tape was used to guide yoga practice. The researcher modified a manuscript from the yoga for health proposed by Kasetsomboon (2001) with permission. It contained guidance for 14 yoga postures, a pranayama and deep relaxation and was approximately 63 minutes in length.

2.3 The researcher engaged in yoga training in order to gain experience and skills at the Yoga Club, Faculty of Nursing, Prince of Songkla University. The researcher practiced yoga following a trainer and tape cassette guidance at least twice in order to be able to practise with tape guidance without the trainer. The research assistant engaged in yoga training with experts at the Yoga Club, Faculty of Nursing, Prince of Songkla University twice attaining a quality standard of practice before data collecting. She was the leader for yoga practice in this study.

Validity and Reliability of the Instruments

Quality of instruments

The Digital blood pressure manometer was checked and calibrated against a standard one. The blood pressure was measured 3 times by the same person using the same method: the patient was sitting in a comfortable position and the pressure cuff was placed two centimeters above the elbow of the same arm. The mean of three measures was used.

The scales for weighing were compared with a standard one and retested to check for quality. The subject's weight was taken clothed without shoes at approximately the same time of the day.

Content validity

The Thai version of the questionnaires (demographic data, and stress assessment questionnaire) were initially tested for validity of content by five experts.

These experts were a medical doctor who specialized in hypertension, a psychiatrist doctor specialized in stress, a nurse specialized in medical nursing, and two nurse instructors who were expert in the areas of psychiatric and medical nursing. Suggestions from the five experts were incorporated in the final revision of the questionnaires. The booklet and yoga cassette guidance were sent to three experts, who had experience in yoga training, for content validation. They were piloted with 3 hypertensive patients in Songkhla province (not the subjects in the study), in order to check the clarity and appropriateness of the booklet and the yoga tape cassette guidance before data collection.

Reliability

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Reliability

The Stress Assessment Questionnaire was tested for reliability with 15 hypertensive patients who met the inclusion criteria, and whose characteristics were the same as the subjects in Songkhla province. Cronbach's alpha coefficient was

computed for ascertained internal consistency to test the reliability of the Stress Assessment Questionnaire. The Reliability coefficient was 0.94, which is acceptable (Polit & Hungler, 1999).

Ethical considerations

The protection of the human rights of the subjects was assured. Those patients who met the requirements were informed of the procedures by reading out the Thai information sheet to them before being asked to participate in this study, and they were able to keep a copy of the sheet if they desired. They were assured of their individual protection of human rights; that they could refuse to join this study without any effect of the continuance of treatment and nursing care they had been receiving; the data arising from the study would be used anonymously to maintain the participants confidentiality and equal rights would be addressed throughout the study especially between the experimental group and the control group. Those wishing to participate signed a form of consent. Those who agreed to participate were informed that there would be no physical or emotional risks as a result of the participation. During yoga practice when they had problems such as headache or dizziness, they were advised to request assistance from the research assistant. At the end of data collection, the cassette tape and booklet were given to the control group to allow them to practice yoga if they desired.

Data collection procedure

Data collection was classified into 2 phases.

1. Preparation phase consisting of four steps

1.1 The researcher reviewed the literature about hypertension, stress, and yoga.

1.2 The researcher engaged in yoga training to be a yoga trainer at the Yoga Club, Faculty of Nursing, Prince of Songkla University.

1.3 Two graduate nurses working in the Outpatient Department, Songkhla Hospital were trained as research assistants. Their roles were as the leader in yoga practice and taking care of subjects during yoga practice. They were trained to be the leader in yoga practice and documented the Yoga Record Form in the experimental group.

1.4 Permission from the Director of Songkhla Hospital was sought to conduct the study and cooperation from physicians, nurses and other related personnel was sought in order to recognize potential subjects from persons with hypertension. Mostly, they came from a screening health examination conducted by staff of Songkhla Hospital, and some came by referral from the Primary Care Unit of Songkhla Hospital. The purposes, procedures, and benefits of the study were explained to the subjects.

2. Implementation phase was performed step by step

2.1 Before intervention

2.1.1 The researcher recruited subjects for both groups from the Outpatient Department, Songkhla Hospital.

2.1.2 The subjects who met the inclusion criteria were invited to participate in this study. The subjects were informed of the purposes, procedures and benefits of the study, assured of their confidentiality, and their right to participate or withdraw from the study at any time without any disadvantages.

2.1.3 After the subjects agreed to participate, written consent forms were signed by all subjects.

2.1.4 Demographic data, and stress assessment questionnaires were administered to the subjects. They were then randomized to experimental group or control group by using the minimized randomization program version 2.01 of Zeller (1997).

2.1.5 After the subjects were randomized to experimental group and control group, the ethical concerns were explained again to them. The experimental group started yoga practice as scheduled three times a week for consecutive 8 weeks. Yoga practice took place three times a week; Monday, Wednesday, and Friday afternoons, 63 minutes per time, at Songkhla Hospital and another group on Tuesday, Thursday, and Saturday afternoons at Bangdan Primary School. They were also told of the need to practice yoga as scheduled three days a week in order to ensure internal validity. They were measured body weight, heart rate, respiratory rate every two weeks and at posttest with SAQ at the end of week eight. For the subjects in the control group, they were normally living activities as they did and the researcher contacted them every two weeks for measurement of blood pressure, body weight, heart rate, respiratory rate, and their changing situation and health behavior during the study. The samples were given the booklet and cassette tape guidance for practising yoga at the end of week eight of data collection if they desired.

2.2 During intervention

2.2.1 The researcher provided additional informational support through the booklet form. Participants listened to the yoga radio cassette tape guidance and practiced yoga together with the research assistant who led the practice. Additional information was available everyday at yoga practice or upon request by the subjects.

2.2.2 A Yoga Practice Record Form was completed by the researcher every time a subject engaged in yoga training as well as other key risk factors, which influence blood pressure were recorded.

2.2.3 Blood pressure, heart rate, respiratory rate, and body weight were recorded before yoga practice on the last day of every second week whereas the control group, blood pressure, heart rate, respiratory rate, and body weight were measured every two weeks by the researcher.

2.3 After intervention (End of week eight).

2.3.1 On the last day of the eighth week, the experimental group was measured of blood pressure, heart rate, respiratory rate, body weight and stress. They were given a copy of the cassette tape for their own use.

2.3.2 At the end of eight week the control group had their final measurements taken; blood pressure, heart rate, respiratory rate, body weight and stress. They were taken through a practice session and given a copy of the cassette tape and booklet for their own use.

Data analysis

The data was analyzed using the Statistical Package of the Social Science (SPSS) for Windows version 10.

1. Descriptive statistics, frequency, percentage, mean, and standard deviation, were used to analyze the demographic data.

2. Mean, standard deviation, and range of total stress score were used to analyze stress levels.

3. Paired t- test for dependent group was used to test the difference of mean stress score before and after receiving intervention in both the experimental and the control group.

4. Independent t-test was used to test difference of stress mean score between the experimental and the control group at pretest and posttest.

5. Repeated measures analysis of variance was used to analyze the difference of systolic blood pressure, diastolic blood pressure, heart rate, and body mass index at initial, 2nd, 4th, 6th and 8th both within group and between groups.

6. The Friedman test and Mann Whitney U were used to analyze the difference in means of respiratory rate at initial, 2nd, 4th, 6th, and 8th week within group and between groups respectively after the assumption of parametric statistic was not met.