CHAPTER 3

RESEARCH METHODOLOGY

The purpose of this study was to evaluate the effects of a 6-session yoga program during pregnancy on maternal comfort, labor pain, and birth outcomes of primiparous women. In this chapter, the methodological aspects of research design, setting, population and sample, instruments, experimental intervention, protection of human subjects, and data management are presented.

Research Design

A randomize controlled trial with an experimental of repeated measures design was used to investigate the effects of the yoga program during pregnancy on maternal comfort, labor pain, and birth outcomes. Experimental control consisted of the inclusion and exclusion criteria, randomized minimization techniques to control for the confounding variables in the study.

Setting

This study took place in the antenatal clinics in two settings at public hospitals in Southern Thailand. These hospitals provide similar standardized care. Currently, the maternity service in Thailand requires all pregnant women to have at least four antenatal care visits (Ministry of Public Health, 2002). However, the number of antenatal visits varies depending on the women's condition and consideration by the

health-care provider. A common recommendation will be that a pregnant woman should use the antenatal service when she recognizes her pregnancy. The woman attends antenatal check-up every month until 28 weeks of gestation, then every two weeks from 28-36 weeks and every week after 36 weeks.

Antenatal care is provided free of charge by public-health services. Generally, obstetric-gynecological nurses or nurse-midwives provide this care in a normal pregnancy, and an obstetrician gives care to a pregnant woman at least once during antenatal care. An obstetrician or gynecologist is responsible for women with a high-risk pregnancy. Women may, however, choose to have their own private obstetricians, and hence have antennal check-up in their doctor's private clinics or in the hospital where the doctor is attached as a medical specialist. This can be at a public or a private hospital. Most births occur in hospital or health-care settings. In general, a woman gives birth where she receives her antenatal care. Where antenatal care is received from a private doctor, the birth will take place in a hospital where the doctor works as a medical specialist (Liamputtong, Yimyam, Parisunyakul, Baosoung, & Sansiriphan, 2005).

Two sub-settings at each hospital were involved in this study, the antenatal clinic and the labor room. The antenatal clinic provides the fundamental services during prenatal visits including: estimation of gestational age, weight monitoring, screening for sexual transmitted diseases, immunization, screening for maternal complications, and evaluation of fetal well-being. Nurses in the antenatal clinic usually educate pregnant women about diet, rest, hygiene, and identifying the immediate symptoms that they should seek treatment for from the hospital. These are bleeding from the vagina, a decrease or absence of fetal movement, a headache, or other related

symptoms. Minor ailments during pregnancy and their management are also included, such as morning sickness, leg edema, and backache.

During the delivery period, pregnant women are admitted if there is evidence of true labor or certain conditions such as ruptured membranes, placenta previa or abruptio placenta. Nurses assess, monitor, and document the data of both the mother and her baby. Without precaution, a small amount (50cc) of unison enema and delivery preparation may be given. Relatives are not allowed to give support to the women after admission. To monitor the labor progression, the assessment of uterine contraction with the fetal heart sounds every 30-60 minutes and vaginal checking approximately every two hours are performed.

Population and Sample

The population in this study consisted of primiparous women who attended the antenatal clinics and delivery rooms of the target settings from January 2005 to February 2006. Pregnant women who met the inclusion criteria were approached and informed of the study. Written informed consent was obtained from those who verbally agreed to participate. In order to reduce bias from systematic selection as it balanced potential confounding (prognostic) variables, and equalized the number of subjects in the two groups (Zeller, Good, Anderson, Zeller, 1997). They were randomly assigned by using the minimized randomization program version 2.01 (Zeller, 1997) (using Microsoft Access 2000) to either the yoga or control group. This method was used to take into account maternal age, education, income, marital status, and trait anxiety.

Inclusion Criteria

The inclusion criteria were as follows: (1) primiparous women, to control for effect of past labor pain, of at least 18 years of age (in accordance with Thai law for signing an informed consent form): (2) ability to communicate and write in the Thai language because this would have an effect on the reliability of responses to the questionnaire; (3) no serious illness or high risk complications during pregnancy (such as pregnancy induced hypertension and bleeding from the vagina) that could be easily threatened by yoga practice; (4) no intention to give birth by cesarean section or painless labor; (5) attending antenatal care from the beginning or at least from the second trimester of pregnancy; (6) agreeing to be involved in either group; and (7) having no prior experience of yoga practice.

Exclusion Criteria

Pregnant women were excluded from the study if they (1) received induction of labor, or a caesarean section; (2) had complications during the study such as pregnancy induced hypertension, bleeding from the vagina, or had complications during labor and after giving birth, and (3) were unwilling to participate at any time during the study.

Sample Size

A previous study, following a similar process of a randomized, single blind, controlled trial, examined the effects of an intervention using supervised yoga and relaxation techniques specially designed for patients with carpal tunnel syndrome on pain intensity (Garfinkel et al., 1998). The yoga-based intervention group took part in a program which used yoga techniques for strengthening, stretching, and balancing each joint in the upper body along with relaxation to help counteract the energy-draining effects of prolonged stress and chronic pain. Therefore, it was used as an example for sample size calculation. The effect size was calculated on the basis of the mean and standard deviation taken from that study. The mean of pain intensity of VAS of the experimental group ($\bar{x}$ = 5, SD = 2.8) was significantly lower than that of the control group ($\bar{x}$ = 2.9, SD = 2.2) at p = .02. The effect size (d) calculated for pain intensity was 0.64. To achieve a power of .80 at alpha .05, an adequate approximation of **n** is given by the following formula (Cohen, 1988, p. 53):

$$\mathbf{n} = \frac{\mathbf{n}.10}{100d^2} + 1 = \frac{1571}{100\,(0.64)^2} + 1$$

Cohen's (1988) Table 2.4.1 on page 55 was used in calculating the necessary sample size value for the given significant criterion of a_2 = .05, which **n.**10 = 1571 and desire power at effect size (**d**) = .10 indicating a minimum requirement of 39 subjects per group. The total sample in the study was 78.

There were only 74 primiparous women enrolled in this study, of which 66 cases were completed in the delivery period (Figure 6). The causes of dropout were

incomplete data due to the active progression of labor as 6-8cm of cervical dilatation on admission, and using a cesarean section due to cephalopelvic disproportion before the delivery period. The reasons for dropping out of the control group were unwillingness to participate any more, precipitate labor, and having a cesarean section due to placenta previa and abruptio placenta before the 1st point of data collection. Thus, the attrition rate in both groups in the current study was 10.81%.

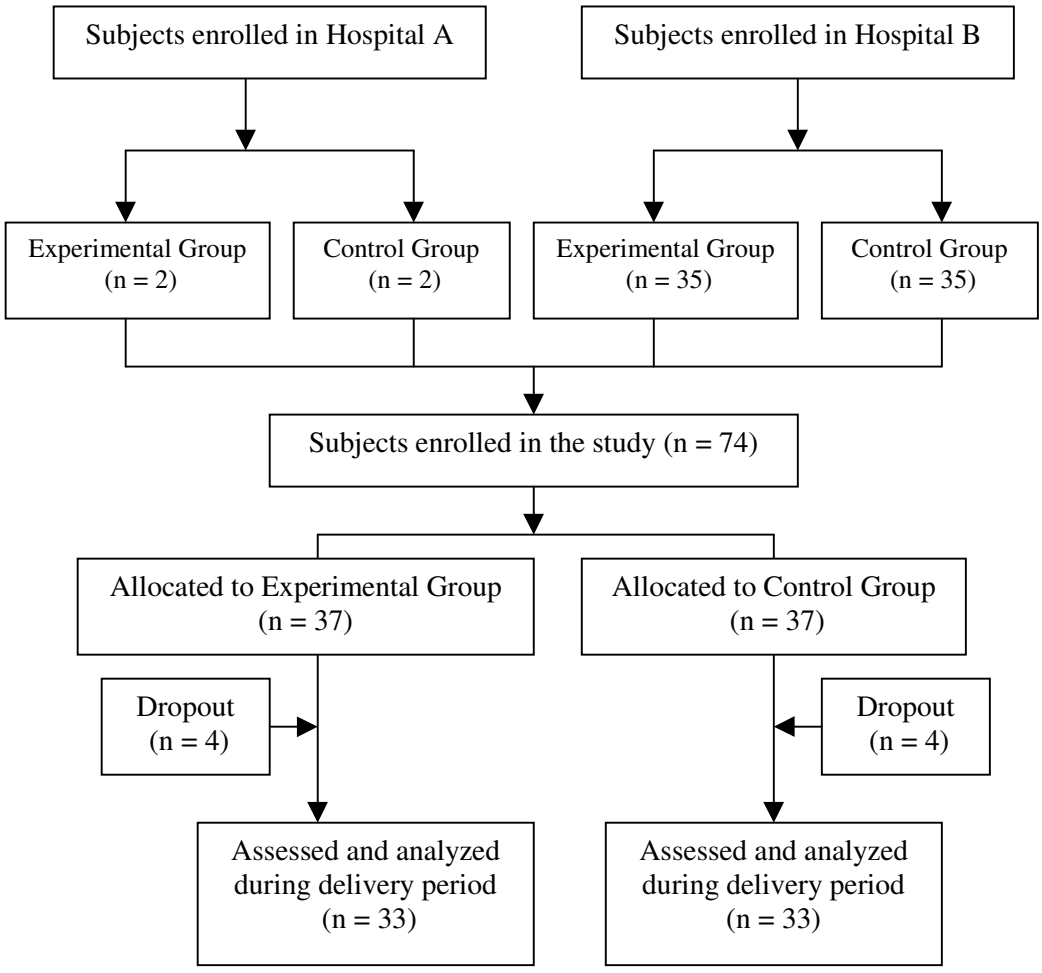

Figure 4 Flow chart of the sample population

Instruments

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

1. An intervention: The yoga program. It was developed based on yoga principles (Balaskas, 2003; Gore, 1997; Kuvalayananda & Vinekar, 1994; Udupa, 1985; Yogendra & Desai, 1994; Yogendra, 1998) and combined with the researcher experience of engagement in yoga training. To evaluate the feasibility of the program intervention, and the study instruments. A pilot study of 3 participants who had the same criteria as in the study was carried out.

In order to ensure the stability of the experimental intervention, the yoga booklet and a cassette were provided for the subjects and used as a reference with instructions to follow. Details of the booklet and the cassette are as follows.

1.1 The booklet for yoga practice consists of information regarding preparation for childbirth and pain management that encompass yogic principles. Steps and benefits of each yoga asana, pranayama, and deep relaxation technique are included (Appendix K).

1.2 The yoga cassette tape guided the yoga practice and combined a sequence of *asana, pranayama, yoga nidra*, and meditation. This cassette tape provides guidance modified from the program yoga for health, which was proposed by Kasetsomboon (2001) for approximately 60-70 minutes.

2. Instruments used for data collection: Demographic Data Form, Trait Anxiety Form, Maternal Comfort During Pregnancy (MCDP), Maternal Comfort During Labor (MCDL), Visual Analogue Scale to Total Comfort (VASTC), Visual Analogue

Sensation of Pain Scale (VASPS), Pain Behavioral Observation Scale (PBOS), and Yoga Practice Record Form.

2.1 The Demographic Data Form (Appendix A) consisted of maternal information including; age, religion, education, marital status, occupation, income, gestational age, serious illnesses or complications during this pregnancy, types of delivery, pain medication, serious illness or complications during and after delivery, and duration of birth and delivery. The newborn's data consisted of gender, gestational age, birth weight and Apgar score at one and five minutes after birth, serious illness or complications and illness that required transferring the newborn to a neonatal intensive care unit. This instrument was developed in two parts; the first part was the demographic data form that pregnant women filled in by themselves after signing the consent forms and before randomized assignment to groups. The second part was the data that was obtained from the mother's records and her infant's birth records by a research assistant in the delivery period.

2.2 The State Trait-Anxiety Inventory, Trait Anxiety Subscale (Appendix B) was used. This is one of the most widely known self-report scales used to measure anxiety, and which has been used extensively as a research and clinical instrument, and originally developed by Spielberger (1983). This scale contained statements for the respondent to choose from to describe how she generally felt, and this was conceptualized as a relatively stable individual difference in proneness to anxiety. Validation of this scale had proved its reliability and sensitivity in measuring anxiety. The trait scale contained 20 items using a 4-point Likert scale; each item could be answered on 1-4 scale, where '1' stood for 'almost never' and '4' stood for 'almost always'. The total gave scores of 20-80. A breakdown was made of baseline score

categories between 20-39, 40-59, and 60-80, which indicated low, moderate, and high trait anxiety scores respectively (Sesti, 2000). Trait anxiety, as a controlled variable, was measured only at the beginning of the study.

2.3 Maternal Comfort During Pregnancy (MCDP) (Appendix C) and Maternal Comfort During Labor (MCDL) (Appendix D) were instruments modified from The General Comfort Questionnaire (Kolcaba, 1992). To do this, positive and negative items were generated for each cell in a two-dimensional grid of the three states of relief, ease, and transcendence, with the four contexts of physical, psychospiritual, social, and environment, in accord with the theory of holistic care. Twenty-four positive items and eleven negative items were compiled, using a Likert-type format that ranged from strongly agree to strongly disagree. Responses were scored from 1 to 6; the higher score indicated more comfort. In this study, it was used with both groups to measure maternal comfort experience at the beginning of the study (26th-28th), 34th, 37th week of gestation, and at the second hour after the delivery.

2.4 Visual Analogue Scale to Total Comfort (VASTC) (Appendix E) was the instrument used to assess maternal comfort of childbirth experience during pregnancy and during labor. This VASTC identified relief, ease, and transcendence to signify factors derived from the previous factor analysis of the General Comfort Questionnaire (Kolcaba, 1992), and total comfort. Stems used for VASTC were: total comfort - “I feel as comfortable as possible right now”; relief - “I have many discomforts right now”; ease – “I am feeling at ease right now”, and transcendence - “I am feeling motivated, determined, and strengthened right now”. Responding to the scales required each participant to place a mark on each 100mm horizontal line that had anchors from the left end of the line in millimeters for scoring total comfort. The current study used

only the total comfort item at each yoga session during antepartum period, and at the same time as measuring the labor pain.

2.5 The Visual Analogue Sensation of Pain Scale (VASPS) (Appendix F) was used to measure the labor pain by self-reporting on a horizontal line. This VAS consists of a 100mm. line anchored by two extremes of pain, “no pain” and “worst imaginable pain”. Severe pain was defined as a mark over 60mm on the VAS, moderate pain as a mark from 40-60mm, and mild pain as a mark under 40mm on the VAS (Maxwell, 1978; Revill, Robinson, Rosen, & Hogg, 1976). Each parturient was asked to put a mark through the line corresponding to the intensity of pain from uterine contractions. The scoring was measured from the distance in mm. from “no pain” to the patients’ marks.

According to Kendrick and Simpson (2001) the active phase of labor averages 4.6 hours, and uterine contractions every 2-5 minutes in regular frequency, are 40-60 seconds in duration, and have moderate to strong intensity by palpation. Maternal physical sensations are increasing discomfort; trembling of thighs and legs, pressure on bladder and rectum, and backache. Maternal behavior consists of: beginning to work at maintaining control during contractions; becoming quieter; and accepting “coaching” efforts of perinatal staff and support persons. There are tremendous changes in the transition phase, with uterine contractions every 1.5-2 minutes of 60-90 seconds duration, and the mother feels the urge to push, and increase rectal pressure. Maternal behavior includes; ambulating; finding difficulty with uterine contractions; being irritable and agitated; being self absorbed and may appear to be sleeping between contractions; asking for more support; verbalizing feelings of discouragement and doubting their ability to cope. Therefore, in this study, VASPS was selected to measure

at the starting point of the data collecting procedure, when the cervical dilatation was 3-4cm. and uterine contractions were of 30-60 seconds duration, and also at the end of each two hours twice in the active phase of labor as presented in Table 1. To prevent response bias, the women were not allowed to see the scales they had marked previously (Phumdoung, 2003).

2.6 The Pain Behavioral Observation Scale (PBOS) was used to record the parturient behavior in pain assessment. This instrument based on the Observation Checklist of Laboring Women's Behavior by Boasoung (1983) (Appendix G). The behavioral checklist consists of five aspects in the observation of vocalization expressed, body movement, breathing control, facial expression, and communication. Each part used a 3-point Likert scale of 3, 2, and 1 scores respectively. It gave scores of 5-15, whereby the low score indicated severe pain and the high score indicated mild pain on the part of the parturient. The assessment was made by the research assistant who recorded the behavior expressed by laboring women at the same time as measuring the VASPS. It was measured from the beginning of the uterine contraction until uterine relaxation, and the results were recorded immediately.

2.7 The Yoga Practice Record Form (Appendix H) is a self-report measuring the length of participation by the experimental group engaged in the practice of the Yoga program techniques during the previous week. Using the Self-Help Intervention Project (SHIP) (Braden, Mishel, Longman, & Burn, 1989) as a guide, the course was organized into six class sessions. The participation actually undertaken by the subjects assigned to the self-help course experimental group was quantified according to the number of class sessions they attended. A record of the subjects' attendance at the sessions served as the instrument for measuring the exposure received. A continuous

scoring scheme was used to represent the exposure variable in the subsequent analysis. Participants in the control group and those in the experimental group who did not attend any of the classes were assigned a value of 0; for the other participants, they were assigned values ranging from 1 to 6, based on the actual number of classes they attended.

In the current study, participants rated how often they practiced and the number of minutes each time. The target was set at 30-60 minutes of practice a day for at least three days a week. This record form was kept in order to determine whether the effect of yoga practice on labor pain, maternal comfort, and birth outcomes would be affected by exposure to yoga practice (duration and frequency). The exposure to yoga practice was measured by the frequency and duration of practicing. The scoring was as follows: if the frequency of yoga practice of 30-60 minutes per day was less than three times per week, the assigned score was 0; if it was 30-60 minutes practice per day three times per week the score was 1; if it was 30-60 minutes practice per day four to five times per week it was 2, and if it was 30-60 minutes practice per day six to seven times per week it was 3. If the duration of yoga practice was 30-45 minutes each time, the assigned score was 1; if it was 46-60 minutes each time it was 2; and if it was 61-75 minutes each time it was 3.

Translation Process

The instruments used for collecting the data in this study were: the Demographic Data Form, the Intrapartum Chart Abstraction Form, the State Trait Anxiety Inventory: Trait Anxiety Form, the Maternal Comfort During Pregnancy Form

(MCDP), the Maternal Comfort During Labor Form (MCDL), the Visual Analogue Scale to Total Comfort (VASTC), the Visual Analogue Sensation of Pain Scale (VASPS), the Pain Behavioral Observation Scale (PBOS), and the Yoga Practice Record Form. These self-report instruments, excluding the Demographic Data Form, PBOS, and Yoga Practice Record Form, were originally developed in the English Language. In order to ensure culturally equivalent versions of these instruments in the Thai language, a translating process using decentering and back translation technique (Brislin, 1980) was conducted. The modified Thai version was judged by a panel of Thai experts to ensure cultural validity. These experts were also asked to rate independently the degree of cultural relevance of each item of the instruments. The results of the ratings were used to compute the cultural validity index (CVI), using the same process as computing the content validity index described by Waltz, Strickland, and Lenz (1991). The CVI of MCDP was 0.90, and MCDL was 0.95.

Content Validity

Thai versions of the Demographic Data Form, State Trait Anxiety Inventory: Trait Anxiety Form, MCDP, MCDL, VASTC, VASPS, PBOS, and Yoga Practice Record Form were assessed for validity of content by five experts. These were an obstetrician and four nurse instructors with expertise in the area of obstetric care or who have had experience in using these or relevant instruments in their research work. Suggestions from the experts were incorporated in the final revision of the questionnaires, visual analogue scales, and the pain behavioral observation scale. The booklet and the yoga cassette tape guide had been sent to two experts who had

experience in yoga training and an obstetrician to assess content validity. In order to check the clarity and appropriateness of the booklet and the yoga cassette tape guide they were piloted with three pregnant women who satisfied the inclusion criterion for the study.

Reliability

1. The maternal comfort questionnaires and trait anxiety subscale were tested with primiparous women who met the inclusion criteria. Cronbach's alpha coefficients were computed to ascertain internal consistency reliability of the trait anxiety and maternal comfort questionnaire. The internal consistency estimate of the translated version of the MCDP was 0.89, and the MCDL was 0.86, which were acceptable for using the newly translated instruments in a different culture. The internal consistency of the State Trait Anxiety Inventory: Trait Anxiety Scale was 0.85.

2. The Visual analogue sensation of pain scale (VASPS) was tested for reliability by using the test-retest method. In this study, women were asked at 3-4cm of cervical dilatation and when uterine contractions were of 30-60 seconds duration, and also at the end of two hours after the first time of the active phase of labor. The internal consistency of the VASPS was 0.74. The visual analogue scale to total comfort (VASTC) was also tested for reliability by using the test-retest method at two-week intervals during pregnancy and at the same time of testing VASPS during labor. The internal consistency of VASTC during pregnancy was 0.91 and during labor was 0.80.

3. The pain behavioral observation scale was tested for internal consistency by using the interraters observed and recorded parturient behavior of the same checklist.

The agreement between the interraters, the reliability coefficient, was determined by the following formula (Selltiz, Wrightsman, & Cook, 1976):

$$\text{Reliability coefficient} = \frac{\text{Number of Agreements}}{\text{Number of Agreements} + \text{Number of Disagreements}}$$

In the current study, the value of agreement of PBOS was 0.80.

The data-collecting plan is shown in Table 1.

Table 1
Data Collecting Plan

Time	Antenatal Period (Week)						Delivery Period			
	26-28	30	32	34	36	37	C x- Dilated 3-4cm (Time 1)	2 hrs after Time 1	2 hrs after Time 2	Two hour after birth
1. Demographic Data Form	√									
2. Trait Anxiety Form	√									
3. Maternal Comfort During Pregnancy (MCDP)	√			√		√				
4. Maternal Comfort During Labor (MCDL)										√
5. Visual Analogue Scale to Total Comfort (VASTC)	√	√	√	√	√	√	√	√	√	
6. Visual Analogue Sensation of Pain Scale (VASPS)							√	√	√	
7. Pain Behavioral Observation Scale (PBOS)							√	√	√	
8. Yoga Practice Record Form	√	√	√	√	√	√				
Birth Outcomes: Length of Labor Apgar Score										√ √

Experimental Intervention

The experimental group received a series of six 60-minute practice sessions of the yoga program at the 26-28th, 30th, 32nd, 34th, 36th, and 37th week of gestation respectively, whereas the control group received standard care. Table 2 shows the yoga program component and the descriptions of the guidelines to be practiced. The yoga program was a combination of two elements: educational activities giving a brief description of basic anatomical structures related to pregnancy and yoga explaining the concepts related to each component. Yoga *asanas*, *pranayama*, *yoga nidra*, *dhyana*, and a combination of *chanting mantra* were practiced harmoniously and in an orderly manner to improve flexibility, muscle force control, endurance, balance and body coordination of the body segment, to reduce fatigue, to relieve some of the discomfort of pregnancy, to promote body awareness and concentration, to elicit a relaxed response, and to promote mental clarity by focusing on the sound of breathing. Additionally, the participants were provided with a booklet and tape cassette for self-study use, which explained the principles and benefits of each yoga practice and asked the mothers to practice at home at least three times a week starting after the first yoga session and continuing until their sixth session. It was expected that each subject would practice yoga for a period of 10-12 weeks. Subjects were informed that they could practice more than three times a week. Compliance in both groups was ensured through the research team making frequent telephone calls, and an additional request was made for subjects in the experimental group to maintain a strict record in a diary. Only the researcher was responsible for the yoga program. All routine hospital procedures were done similarly to the procedures used for the control group. Subjects

in the control group received routine hospital procedures and standard nursing care by the staff nurses, and the researcher engaged them in casual conversation for 20-30 minutes during each session. Table 3 represents the Yoga program session objective as a guideline to practice.

Table 2

Yoga program practice components

Activity	**Description**
Education (5-10 min.)	Subjects were given a brief description of basic anatomical structures that related to pregnancy and birth. The goal was to facilitate a greater understanding of the physical function during pregnancy and labor.
Body awareness (5-10 min.)	Subjects were guided through awareness of various parts of their body and their thoughts. The aims were to promote awareness of body sensation, position, and awareness of the activity of the mind.
Pranayama (breathing exercise) (5-10min.)	Voluntary breathing activities were taught and practiced, such as, a complete breath of 3 parts. The goals were to promote awareness of the sensation of the breath in the body, and awareness of how the breath could facilitate movement of body segments, and to promote concentration.

Table 2 (continued)

Yoga program practice components

Activity	**Description**
Asana (physical poses) and Pranayama (breathing exercise) (15-20 min.)	Subjects were instructed and assisted as necessary in performing a variety of modified yoga poses related to each Yoga program session objective. The goals were to improve flexibility, muscle force, endurance, balance, and coordination of the body segments. It is also restored to the body-mind, its fundamental condition of the well-being, ease, and vibrant alertness.
Yoga Nidra (relaxation) (5-10 min.)	The subjects were instructed to listen and follow guide imagery tape incorporation visualization and then allowed to rest in silence. The goal was to elicit a relaxation response.
Meditation (5-10 min.)	The subjects were instructed to be silent, focusing on the sound of breath while sitting or lying down. The goal is to promote mental clarity (clear one's mind of extraneous thoughts).

Table 3

Yoga program sessions

Session	Focus
1. Establishment of a solid foundation	The educational purpose was focused on information about a brief description of basic anatomical structures related to pregnancy and birth, everyday posture harmony with the pregnant state, and warm up exercises.
2. Promoting comfort	The focus of this session was on the asanas for releasing tension.
3. Activating the power of birth passage	The focus was on essential exercises, especially on the pelvis, in order to prepare the baby for the birth.
4. Knowing the flow of life and birth	It focused on the pranayama or breathing techniques and visualization for birth.
5. Creating better balance	It emphasized the stability of mind-body connection.
6. Creating peace of mind	This session focused on the feeling of relaxation.

Preparation for the Researcher and Research Assistant

The researcher had been engaged in yoga training at the Yoga Club, Faculty of Nursing, Prince of Songkla University. In addition, the researcher practiced yoga following the tape cassette guide at least two times in order to gain experience and skill in delivering the yoga program.

There was one research assistant who had a bachelor's degree in education assisted in conducting the Yoga program for pregnant women, and also collected data in the antenatal period. Before the data collection, a research assistant engaged in yoga training with experts at the Yoga Club of the Faculty of Nursing, Prince of Songkla University at least two times to attain a good standard of yoga practice.

The other research assistants were the nurses who had at least one year's experience in taking care of laboring women. The researcher trained all the research assistants who helped in both the antenatal and the delivery periods in all aspects of data collecting. The instructions for recruiting potential participants, administering the instruments, and issues pertaining to informed consent and the use of human subjects, were all raised and discussed. Furthermore, the researcher supervised each research assistant in collecting data from the first few subjects. Practical problems, and a written document related to collecting procedures and relevant issues, were discussed and resolved and suggestions were noted for the further collecting of data.

This study took place in two settings in antenatal and labor units at two public hospitals. There was a study data collector manual available in which contained information essential to standardized data collection. In addition, antenatal clinic staff and data collectors working as a team in the labor room from each hospital attended an

orientation providing an overview of the study before the program began. This process included a discussion of informed consent; confidentiality and data collection issues; and a discussion of the key concepts and variables used in each of the data collection tools. Each tool was included in the study manual, and oral presentations of the content, with specific examples of how to record the data correctly, were given in the preparation phase. Timing of delivery and birth could not be exactly predicted, whether during the morning, evening or night shifts. However, the primary contact person and the data collecting nurses had the opportunity to meet and get to know one another at the orientation session, which was also used for planning in connection with the continuing collection of data from subjects. They were reminded of the importance of their participation as data collectors in this study. After the study finished, monetary incentives were paid (100 Baht per case) to the data collectors and a letter of thanks was sent.

Procedures

When the research proposal had been approved, the researcher met the nurses at the antenatal clinics to explain the purpose and the nature of the study. Potential participants were accessed through the registration lists at the antenatal clinics. They were approached and informed about the investigation of the effects of the yoga program during pregnancy, and during labor and delivery. They were invited to become involved in the study by assessing the response to the experimental intervention at each scheduled appointment and during the labor period. They were assured that they would receive the same standard care from the hospital as those who

did not participate in the study, and they would receive a monetary incentive of 200 Baht for participating in the program. Both groups would receive a letter of thanks for their participation. After verbal agreement to participate was obtained, the informed consent form (Appendix I) was read and explained to the subjects. The informed consent form included information regarding the study's purposes, time commitment, procedure to be used, and the right to withdraw at any time without affecting the status or the care they received.

Protection of Human Subjects

In relation to the rights of human subjects, the Ethical Research Committee, Faculty of Nursing, Prince of Songkla University, and the hospital directors and the hospital ethical committees approved the research proposal. The researcher approached the eligible participants and gave them explanations related to the study. They were also given time for asking questions and making decisions as to whether or not to participate in the program. Contact addresses and telephone numbers were also exchanged.

Subjects were assured as to the confidentiality of their personal information. A coding number was used to identify each subject. Only the researcher and research assistants were able to access the data. When the study was completed the data was destroyed and the reporting of all data would then be presented as a group.

The pregnant women were provided with the researcher and research assistant's name, office, and mobile phone number so that they could request assistance if they had problems such as dizziness and headache during yoga practice.

Subjects in the experimental group were advised to take certain precautions. For example, it was important for them to check their health status with a midwife or obstetrician before starting yoga practice, and to avoid poses that over-stretched the muscles, because this might cause strain, tension or pain. Pregnant women were advised to observe carefully any signals to slow down or modify poses during practice. They were told to stop practicing and call a midwife or physician immediately if at any time they began to bleed. They were expected to record the problems or complications from the yoga practice in a field note for further analysis. Throughout the study, no subjects in the experimental group encountered any of the anticipated problems. Moreover, no adverse effects were found in the fetus or newborn in relation to the precautions given about thermoregulation.

Threats to Internal Validity

Internal validity is defined as the observed effect of the dependent variable that is actually due to the action of the independent variable, and not due to the extraneous variables (Cook & Campbell, 1979). Randomization tends to produce comparable study groups with respect to known and unknown risk factors, and removes investigator bias in the allocation of participants, and guarantees that statistical tests will have valid significance levels (Friedman, Furberg, & Demets, 1998). This section describes the potential threats to internal validity in this study and the strategies used for controlling them.

History refers to events occurring during the course of the study (between the pretest and the posttest), between and within the experimental and the control group

that might have influenced the final outcomes of the research. Events such as the possible changes in nursing care, procedures, or treatment in the hospitals might have occurred.

There were two settings at public hospitals used in this study. They were therefore organized in accord with public sector provisions required by the Thai Ministry of Public Health. These hospitals have similar standards of care. If the standard care, procedures, or treatments in the hospitals were changed, the effects of the changes were the same for all the treatment carried out at these hospitals.

In order to minimize influences between or within the experimental and control groups in the different settings and from the beginning to the end of the study, the manipulation of core practicing of the intervention and data collecting, the orientation given to the research assistants, and the randomization of assigning the subjects into either the experimental or the control group were followed. Each pregnant woman experienced the same global pattern because of this history effect.

Maturation was defined as a threat when an observed effect might be due to such influences as the subjects being older, wiser, stronger, more experienced, and more fatigued between the pretest and posttest, and when this maturation is not the focus of the study. Furthermore, the pregnant state involves change, which occurs in the individual as a function of time in the natural process with little or no nursing or medical intervention. Therefore it was assumed that the randomization procedure at the starting point of 26th-28th week gestation guaranteed that this threat was equally distributed among subjects in both groups.

Testing was defined as the learning that resulted from being tested at pretest that affects responses to the test at posttest, regardless of the introduction of the

treatment variable. In the current study, there were six timed sessions of treatment procedure during pregnancy. One item of VASTC was used for a two-week interval from Time 1 to Time 5, and a one-week interval from Time5 to Time 6, without the subjects seeing the previous score. Along with the VASTC, MCDP for four-week interval measurement was used to get more understanding of holistic comfort. Thus the long period of time might prevent the subject from remembering the previous answers. Moreover, the pregnant women were randomly assigned to either the experimental group or the control group; each participant experienced the same testing conditions.

Instrumentation was a threat when an effect might be due to a change in the measuring instrument between an initial point of data collection and a subsequent point, and not to the treatment's differential impact at each time interval. Changes that occurred in the recording of the observers and raters, who could potentially make changes in the measurements of the dependent variables, might affect internal validity. In this study the subjects were randomly assigned to either the experimental group or control group; the same instruments, questionnaire and visual analogue scale were used for each pregnant woman at each time point of the data collection. Clear guidelines for using POBS were also provided during the delivery period. Therefore, this threat was minimized in this study.

Statistical regression was the movement of a score to the mean of a distribution. In this study, subjects were randomly assigned to either group with an equal probability of being assigned to the different groups of the study. Subjects were not selected on the basis of high or low scores of dependent variables.

Selection bias was a threat, since the selection of subjects on a nonrandom basis might produce differences in the experimental and control group. Using randomization removed investigator bias in the allocation of participants in this study.

Interaction with selection, such as selection-history, selection-maturation, or selection-instrumentation could cause spurious treatment effects. In the study under review, these threats were prevented by the randomization techniques used to assign subjects to the experimental or control group, which was assumed to guarantee equal distribution of subjects to the groups. This would make these biases unlikely.

Attrition was the nonequivalent loss of subjects between the experimental and control group. In recruiting participants for the study, both groups were provided with clear pre-experiment details of the requirements and importance of the work. Hence, they were informed in positive terms of the objectives of the study, and they were told that, because of the requirements of the research, they should only volunteer if they were willing to participate in either of the groups. They were told they would be assigned randomly to the experimental or the control group, and the importance of random assignment was briefly explained.

Some strategies were designed to diminish barriers to fully participating in the study. These included: monetary reimbursement to research participants for their time or for transport expenses (200 Baht per case). A small gift for the baby after birth was also offered to subjects who volunteered to participate in the program. Furthermore, flexible times of appointment for each session were set. These were timed to coincide with the date for follow-ups for antenatal routine care, or at a convenient time as close as possible to the scheduled time of the yoga program.

To minimize the rate of attrition, the researcher kept in touch with the control group by spending around 30 minutes on a regular basis during each scheduled appointment. The eligible number of participants in this study was a total of 74, which remained the same until they finished the six sessions of the program. However, during the delivery period the number dropped to 66 subjects because of the exclusion criteria. The attrition rate in both groups of the current study was 10.81%.

Diffusion or imitation was the sharing of ideas about the treatment involved and the program by subjects with each other and between both groups. Thus respondents in one treatment group may acquire information intended for others. In this study, this bias was minimal because the researcher used strategies to reduce this threat, as stated earlier. Another possible remedy for such diffusion of knowledge of treatment is blinding, which in this study could be only be due to a single blind of masked assessors due to the nature of the intervention. Consequently, the participants and the hospital staff were only informed that there were two groups in this study: the experimental and the control group. No nurses or subjects from the antenatal clinic or in the labor room discussed treatment with subjects in a different group. The researcher was aware of these issues and vigilant in monitoring both participants and nurses during the course of the study. The researcher also asked the nurses not to discuss the study procedure with other pregnant women. It was assumed that standard care was given equally to both groups by the hospital staff, and they supported the protocol for the group to which each participant was assigned.

Compensatory equalization of treatment was the conscious effort to compensate for less desirable care. This could mean nurses giving better standard care to the control group than to the experimental group. In this study, though nurses,

physicians, or hospital administrators might perceive that the experimental group was getting patently superior treatment to standard care, as the researcher knew, none of them consciously interfered with the study. The researcher also made it clear to them that the definite advantage of the treatment was still uncertain. Asking nurses not to discuss the study procedure with other patients was another way to prevent this threat, and it was also important to be vigilant in monitoring both physicians and nurses during the course of the study.

Compensatory rivalry and resentful demoralization by respondents receiving less desirable treatments could be an issue. The situation of compensatory rivalry is one in which subjects in the control group might be motivated to attempt to reduce or reverse the expected differences brought about by the experimental treatment. The resentful demoralization of subjects in the control group is shown by way of reduced effort compared with the other group. Both of these threats could have artificially affected the results and wiped out the expected differences. In this study the subjects in the experimental group scored higher on both VASTC and MCDP at Time 1 than did subjects in the control group, and there were no significant differences in the relative changes in maternal comfort during pregnancy. Thus, subjects in the control group were not expected to compete with the experimental group, and pregnant women in the control group were not likely to be demoralized when compared with the experimental group. However, those in the control group knew that they were not getting an extra intervention. The researcher was aware of these issues.

Data Management

In order to decrease threats to internal validity, the instruments were composed of instructions and a brief explanation of the data record (Roberts, Anthony, Madigan, & Chen, 1997). Research assistants checked all questionnaires. If data were missing unintentionally, women were asked to add more data to complete their submissions. Each day the researcher checked the data collection instruments for accuracy, and coded all data. Metric calculations were used with the same ruler for the VASTC and VASPS in millimeters. In the delivery period, the subjects were told to be sure to place marks on the lines in both of these scales in order to prevent mistakes.

During data entry, the researcher 'cleaned' them to decrease the errors. The descriptive statistics were assessed to note the characteristics of the data and the missing data to ensure the validity of the research findings. The SPSS program (version 13.5) was used to process the data. The means, standard deviations, frequencies, and percentages were computed to describe the characteristics of the samples in terms of demographic characteristics and other personal data. An independent t-test for the interval levels, and a chi-square analysis for nominal data, was used to determine group differences.

Assumption Testing of the Statistical Analyses

First, the underlying assumptions for the t-test were examined. The dependent variables and the control variable of trait anxiety were treated as continuous data. The measurement of VASTC over six sessions and MCDP over three time points during

pregnancy, and VASPS, VASCT and PBOS across three time points during the active phase of labor, together with the using of MCDL two hours after birth, were examined for normality. No evidence of skewness, kurtosis, or univariate outliers for these variables was found. Levene's test for equality of variances showed homogeneity of variances between groups. Therefore, the underlying assumptions for the t-test were met.

Second, the underlying assumptions for repeated measures of ANOVA were tested. The statistic was structured with the between subjects factor for the experimental group and the control group. Within-subjects factors are: 6 time levels of maternal comfort by using visual analogue scale over the pregnancy period; 3 time levels of maternal comfort by using maternal comfort questionnaires at 26th-28th, 34th, and 37th week; and 3 time levels of maternal comfort, labor pain, and behavioral observational pain during labor. The dependent variables of maternal comfort during pregnancy and during labor, as well as the dependent variables of labor pain and behavioral observational pain, were normally distributed. The within-subject correlation from the repeated measures was modeled using a compound symmetric covariance structure. In this study, the results showed that the variances of the differences between levels were significantly different. In order to produce a valid *F*-ratio, the estimates of sphericity used to correct the degrees of freedom were Huynh-Feldt correction when $\varepsilon > 0.75$ or the Greenhouse-Geisser correction when $\varepsilon < 0.75$ (Field, 2005). Furthermore, the homogeneity of covariance assumption, which is inherent to analysis of covariance, was tested by constructing the interaction terms of time by group to assess differential time means between groups. The results revealed that the interaction between the independent variable of treatment and the covariance

were not significant. This meant that the slope of the regression line in each of the cells is similar (Bryman & Cramer, 2001).

Third, the underlying assumptions for regression analysis were tested. In the study, regression analysis was aimed at testing whether a relationship between the outcome (mean difference of 1st and 6thVASTC) and explanatory variable (frequency and duration of yoga practice) existed for the yoga group. The mean of the regression-standardized residual based on a histogram was apparently zero. Examination of residual scatterplots shows no violation of the assumption of homoscedasticity. The standardized predicted values and standardized residuals had a mean of zero and amost zero with a standard deviation of approximately or equal to 1. This was as expected if they were normally distributed, and congruence with the P-P plot of studentized deleted residual showed a normal distribution. No autocorrelated residuals were found based on the Dubin-Watson value (1.447). The relation between tolerance value of 0.894 and VIF value of 1.119 confirmed their lack of multicollinearilty. In terms of outliers, the Cook's distance was 0.174, similar to the accepted leverage value of 0.195, indicating that there were no influential outliers in the model.

Statistical Analyses of Hypotheses Testing

The hypothesis testing in the current study and the statistics used with alpha 0.05 and a two-tailed-test were as follows.

Hypothesis 1: "The mean score of labor pain of the experimental group is lower than that of the control group."

To determine whether the experimental group had less pain over three time points, repeated measures of ANOVA of VASPS and PBOS were used.

Hypothesis 2: **"**The mean score of maternal comfort during labor of the experimental group is higher than that of the control group."

To determine whether the experimental group had more comfort over three time points, repeated measures of ANOVA of VASTC and an independent t-test of MCDL were used.

Hypothesis 3: "The mean score of birth outcomes (length of labor, Apgar score) of the experimental group is better than that of the control group."

Sub-hypothesis 3.1: "The length of labor of the experimental group is shorter than that of the control group."

Sub-hypothesis 3.2: "Newborns in the experimental group are not at higher risk than the newborns in the control group."

To determine whether the experimental group had better scores of birth outcomes; (length of labor and Apgar score at 1st and 5th minute), an independent t-test was conducted.

Hypothesis 4: "The mean score of maternal comfort during pregnancy of the experimental group is higher than that of the control group."

To determine whether the experimental group had more comfort over six time points assessed by VASTC and three time points assessed by MCQ, repeated measures of ANOVA were used.

Hypothesis 5: "Pregnant women who undertake a greater quantity of yoga practice (more frequently and for a longer period of time in minutes) have higher maternal comfort than those who undertake a lesser quantity of yoga practice."

To determine whether participants who had more quantity of yoga practice during pregnancy had higher maternal comfort than those who had less yoga practice, regression analysis was undertaken.

Conclusion

A randomized controlled trial was conducted to evaluate the effect of the yoga program on maternal comfort, labor pain, and birth outcomes in primiparous women. Randomized minimization techniques were used controlling for the five potential confounding variables of maternal age, education, income, marital status, and trait anxiety. The experimental group received a series of six 60-minute practice sessions of the yoga program at the 26-28th, 30th, 32nd, 34th, 36th, and 37th week of gestation respectively, whereas the control group received standard care. Repeated measures of ANOVA (split-plot design) were used to test the differences in labor pain and maternal comfort during labor. To determine whether the experimental group had better scores of birth outcomes in length of labor and Apgar score, an independent t-test was used. During pregnancy, repeated measures of ANOVA (split-plot design) were used to investigate the differences in maternal comfort during pregnancy and regression analysis was used to determine the effectiveness of the yoga program.