THE EFFECT OF HEARTBURN MANAGEMENT PROGRAM ON FREQUENCY AND SEVERITY OF HEARTBURN IN PREGNANT WOMEN

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OF THE REQUIREMENTS FOR THE DEGREE OF
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Thesis
entitled

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ABSTRACT

The purpose of this study was to determine the effects of a heartburn management program on the frequency and severity of heartburn in pregnant women. A symptom management model of Dodd et al. (2001) was used as the conceptual framework of the study. The sample consisted of 48 pregnant women who attended a prenatal clinic at Ramathibodi Hospital. They were divided into an experimental group and a control group. The experimental group received the usual care from nursing staff and heartburn management program from the researcher, whereas the control group received only the usual care from nursing staff. Data collection took place during January to May 2015 by using demographic data questionnaire, heartburn experience questionnaire and heartburn recording form. Descriptive statistics and inferential statistics were used to analyze the data.

Findings of the study revealed that the frequency and the severity of heartburn in the experimental group after finishing the heartburn management program decreased with statistical significance ($p < .05$). In addition, the frequency and the severity of heartburn in the experimental group were less than those in the control group with statistical significance ($p < .05$).

Based on the results of the study, a heartburn management program could be utilized as the guideline of nursing care plan for pregnant women suffering from heartburn to reduce the frequency and the severity of the symptom.

KEY WORDS: HEARTBURN MANAGEMENT PROGRAM/ FREQUENCY OF HEARTBURN/ SEVERITY OF HEARTBURN

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ผลของโปรแกรมการจัดการอาการแสบร้อนยอดอกต่อความถี่และความรุนแรงของอาการแสบร้อนยอดอกในหญิงตั้งครรภ์

THE EFFECT OF HEARTBURN MANAGEMENT PROGRAM ON FREQUENCY AND SEVERITY OF HEARTBURN IN PREGNANT WOMEN

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บทคัดย่อ

งานวิจัยนี้มีวัตถุประสงค์เพื่อศึกษาผลของโปรแกรมการจัดการอาการแสบร้อนยอดอกต่อความถี่และความรุนแรงของอาการแสบร้อนยอดอกในหญิงตั้งครรภ์ โดยใช้กรอบทฤษฎี Symptom Management Model ของดอดด์และคณะ (Dodd et al., 2001) เป็นแนวทางในการศึกษา กลุ่มตัวอย่างเป็นหญิงตั้งครรภ์ 48 ราย ที่มารับบริการที่คลินิกฝากครรภ์ โรงพยาบาลรามาธิบดี แบ่งเป็นกลุ่มควบคุมและกลุ่มทดลอง กลุ่มทดลองได้รับการพยาบาลตามปกติจากพยาบาลประจำการร่วมกับโปรแกรมการจัดการอาการแสบร้อนยอดอกจากผู้วิจัย ในขณะที่กลุ่มควบคุมได้รับการพยาบาลตามปกติจากพยาบาลประจำการเพียงอย่างเดียว เก็บรวบรวมข้อมูลระหว่างเดือนมกราคม ถึงเดือนพฤษภาคม พ.ศ. 2558 โดยใช้แบบสอบถามข้อมูลส่วนบุคคล แบบสอบถามประสบการณ์การมีอาการแสบร้อนยอดอก และแบบบันทึกอาการแสบร้อนยอดอก วิเคราะห์ข้อมูลโดยใช้สถิติเชิงบรรยายและสถิติอ้างอิง

ผลการศึกษาพบว่าความถี่และความรุนแรงของอาการในกลุ่มทดลอง เมื่อสิ้นสุดโปรแกรมลดลงอย่างมีนัยสำคัญทางสถิติ ($p < .05$) นอกจากนี้ ความถี่และความรุนแรงของอาการแสบร้อนยอดอกในกลุ่มทดลองน้อยกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ ($p < .05$)

ผลการวิจัยครั้งนี้แสดงให้เห็นว่าโปรแกรมการจัดการอาการแสบร้อนยอดอก สามารถนำมาใช้เป็นแนวทางในการวางแผนการพยาบาลหญิงตั้งครรภ์ที่มีอาการแสบร้อนยอดอก เพื่อลดความถี่และความรุนแรงของอาการ

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CHAPTER I
INTRODUCTION

Background and Significance

Pregnancy causes both anatomical and physiological changes in order to maintain bodily balance and support the growing fetus until childbirth (Sakonratanakul & Khanobdee, 2007). The changes in pregnancy may result in discomfort among pregnant women. Even though the discomfort is not life threatening but severity of symptoms can lead to health problem in some case (Sakonratanakul & Khanobdee, 2007; Sakunneeya, 1997). Heartburn in pregnancy is one of the unpleasant symptoms which pregnant women always suffer from. Review of literature indicated that 30-50 percent of pregnant women experience this symptom, and in some countries the prevalence of heartburn is about 70-95 percent (Audu & Mustapha, 2006; Khresheh, 2011; Knudsen, Lebech, & Hansen, 1995; Naumann, Zelig, Napolitano, & Ko, 2012).

Naumann and others (2012) found that the occurrence of heartburn in pregnancy among native Americans, Caucasians, African-Americans and Asians pregnant women were 89.2, 84.3, 77 and 75 percent, respectively. In addition, the frequency and severity of heartburn increased with gestational age; from 22 percent in first trimester to 36 percent in the second trimester and up to 72 percent in the third trimester of pregnancy (Marrero, Goggin, de Caestecker, Pearce, & Maxwell, 1992; Richter, 2005). However, there is no formal report about the occurrence of heartburn in pregnancy in Thai pregnant women.

Heartburn in pregnancy is an unpleasant symptom occurred due to the changes during pregnancy. The symptom is characterized by a painful burning sensation in esophagus and epigastrium, belching, reflux of acid, bile, and gastric content. Pregnant women usually start to experience heartburn around the fifth month of pregnancy. The symptom generally occurs in short period of time and related with meals. Severity of heartburn is varied, from a feeling of discomfort to so unbearable

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that interfere eating and rest of pregnant women. The frequency and severity of heartburn tend to increase as pregnancy progress (Neilson, 2008; Richter, 2005).

Review of literature indicated that almost half of pregnant women experienced at least one episode of heartburn during third trimester of pregnancy. Severity of heartburn ranged from mild to severe. In addition, heartburn was related to meals, usually emerged after dinner. Some of pregnant women who experienced heartburn could tolerate this symptom. However, the discomfort resulted from the symptom interfere daily activities and sleep pattern of some pregnant women (Audu & Mustapha, 2006; Khresheh, 2011; Nagler & Spiro, 1961).

The causes of heartburn in pregnancy are possibly from two major causes. The first cause is hormonal change, especially the elevation of progesterone hormone. Progesterone plays a major role in relaxing lower esophageal sphincter (LES) and leads to acid and bile regurgitation. As commonly known, mucosa lining in the esophagus is unlike in the stomach; therefore acidity in gastric content could easily irritate it and create burning sensation (Monti, 2007). Moreover, progesterone decreases movement of small intestine and delays gastric emptying time, ultimately reflux of gastric content occurs (Lind, Smith, Mc Iver, Coopland, & Crispin, 1968; Nagler & Spiro, 1961; Richter, 2005; Van Thiel, Gavaler, Joshi, Sara, & Stremple, 1977). The second key factor contributes to heartburn is the interference of abdominal organs by the enlarged uterus, gradually intra-abdominal pressure increased and leads to the symptom (Monti, 2007; Richter, 2005).

In addition to the key factors mentioned above, review of literature also reported that there are several factors related to heartburn in pregnancy. These factors included maternal age, number of pregnancy, food intake and food habits, lifestyles, and races (Audu & Mustapha, 2006; Bassey, 1977; Bor, Kitapcioglu, Dettmar, & Baxter, 2007; Knudsen, Lebech, & Hansen, 1995; Naumann et al., 2012; Oliver, Davies, & Dettmae, 2011).

The effect of heartburn in pregnancy could be summarized as the following: discomfort, dietary and sleep pattern disturbance, interfere with daily activities, and decrease quality of life (Monti, 2007; Naumann et al., 2012; Neilson, 2008; Suzuki, Dennerstein, Greenwood, Armstrong, & Satohisa, 1994). Pregnant women who have severe heartburn will have extreme weight loss, dehydration, and if

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they do not get proper management, the symptom would progress to gestro-esophageal reflux disease and esophagitis (Bor, Kitapcioglu, Dettmar, & Baxter, 2007; Richter, 2005).

Heartburn is viewed as a common symptom occurred among pregnant women during second and third trimester of pregnancy. There is no specific measure to alleviate this symptom. Pregnant women who experience severe heartburn will receive medical treatment, however, maternal and fetal safety is the major concern of medication used (Neilson, 2008). Review of literature indicated that some pregnant women used their own ways to get rid of heartburn, for instance using antacid or herbs (Khresheh, 2011). Nevertheless, there is no evidence support about the effectiveness and the safety of strategies used by the pregnant women (Neilson, 2008). Although heartburn in pregnancy is mainly caused by the changes during pregnancy, it is crucial to reduce or eliminate the factors that contribute to this symptom. Pregnant women in the second and third trimester of pregnancy should be advised to modify lifestyles and avoid risk behaviors which could trigger the occurrence of heartburn (Monti, 2007; Neilson, 2008; Richter, 2005; Sakonratanakul & Khanobdee, 2007).

Ramathibodi Hospital is a tertiary care facility located in the central of Bangkok, Thailand. The care provided in prenatal clinic is based upon antenatal care standards and safe-motherhood initiatives. Health promotion, risk prevention and strategies conducive to positive pregnancy outcome are major concerns for health care providers. Similar to other hospitals, there is no formal report about the occurrence of heartburn in pregnancy. However, the researcher had explored in the prenatal clinic prior to the study and found that approximately one-third of pregnant women who came to prenatal clinic at Ramathibodi Hospital experience heartburn. Nowadays, there is no specific instruction for the expectant mothers who face with heartburn; therefore, the researcher as a nurse is interested to study about heartburn in pregnancy and developed a nursing program based on symptom management model of Dodd and others (Dodd, Janson, Facione, Faucett, Froelicher, & Humphreys et al., 2001). The program developed aim to help pregnant women who experience heartburn to decrease frequency and severity of this unpleasant symptom and ultimately improve physical, psychological well-being, and quality of life.

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Conceptual framework

The researcher used the symptom management model of Dodd and others (2001) developed from Symptom Management Model of Larson and others (Larson et al., 1994) as conceptual framework. According to the model, symptom is a perception of an individual about unpleasant feeling, suffering, bodily and mental change, as well as cultural and social change. The symptom occurred makes an individual comes to see a physician for investigation and treatment. Dodd and others (2001) stated that symptoms are experiences which cause changes in bio-psychosocial functions, sensation, or cognition of an individual. In this study, heartburn is unpleasant symptom affects bodily functions and daily life of pregnant women. A pregnant woman who experiences this symptom will feel suffer. There are three major concepts in the symptom management model: symptom experience, symptom management, and strategies and outcome, all of which are related to each other (Dodd el al., 2001). The details are described as follows:

Symptom experience

Symptom experience is a perception of individuals to the symptom they are suffering from. It is dynamic and changeable. There are three dimensions of symptom experience: perception of symptom, evaluation of symptom, and response of symptom. The three dimensions influence on each other.

1. Perception of symptom is the awareness of an individual when the change or abnormality occurs in the body. Personal characteristics, symptoms characteristic, and environment influence individuals' perception of symptom. Perception of symptom can be assessed by the interview or using the questionnaire. Based on the theory of Dodd and others (2001) perception of symptom contributes to effective symptom management strategies. Review of literature showed that pregnant women viewed heartburn as a common unpleasant symptom could be found during pregnancy; therefore, they did not describe the symptom to the health personnel. Eighty-five percent of the pregnant women tried to tolerate the symptom or chose their own ways to manage the symptom (Khresheh, 2011).

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2. Evaluation of symptoms is the assessment of an individual to the symptom occurred. The individual will consider about causes, frequency, severity,

location, description of the symptom, and impact of symptom on daily life before evaluation of symptom. The study revealed that pregnant women viewed heartburn as a painful burning sensation in the esophagus and epigastrium, besides burning sensation, belching and reflux of acid and gastric content were found. The symptom was periodically occurred and related to meals. Moreover, frequency and severity of heartburn increase along with gestational age, and finally heartburn affected daily life (Monti, 2007; Naumann et al., 2012).

3. Response to symptoms is an expression of individuals when experiencing symptom. The response could be physiological response, psychological response, sociocultural response, or behavioral response. Review of literature disclosed that heartburn in pregnancy affect daily living of pregnant women. The pregnant women who experienced the symptom had to modify their lifestyles, dietary patterns, or postures. Pregnant women with severe heartburn had to avoid eating or drinking in order to minimize heartburn (Khresheh, 2011; Monti, 2007; Naumann et al., 2012; Neilson, 2008; Suzuki et al., 1994).

Dodd and others (2001) mentioned that symptom experience influences symptom management strategies. The feeling of heartburn in pregnancy ranged from uncomfortable until so unbearable and made pregnant women could not eat or rest. The pregnant women who experienced this unpleasant symptom tried to modify their lifestyles and adjust dietary pattern. However, symptom experience in each individual is different; therefore, it is necessary to assess symptom experience of heartburn in each pregnant women in order to find out the suitable symptom management strategies.

Symptom Management Strategies

Symptom management strategies are the methods used by an individual to cope with the symptom. Symptom management is a dynamic process; therefore, the strategies used could be changed over the period of time. It depends on an individual's perception and acceptance. The fundamental concept of this theory is that troublesome symptom should be resolved upon occurring. It is necessary that the strategy control symptom experiences and symptom outcomes. The goals of symptom management are deviating the symptom and making negative effects of the symptom

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by using 1) biomedical strategies e.g., taking antacid 2) professional assistance e.g., receiving advice to avoid risk factors; 3) self-care strategies e.g., modifying of lifestyles and dietary habits, taking antacid bought over the counter or using herbs. Symptom management is resulted from assessment of symptom experiences identified by patients to determine appropriate management. It is important that patients and health care provider shared common understanding and be able to specify details of management strategies: what, when, where, why, how, whom and then. The health care provider educates patients, equips them with advice and skills in self-symptom management and encourages them to follow advice to enhance their potential in self-care and self-symptom management. Based on the theory of Dodd et al. (2001), an individual has a potential for self-care; if not health assistance is needed, sufficient knowledge and skills to help enhance their potential in self-care.

Heartburn in pregnancy is an unpleasant symptom which affects the wellness of pregnant women. Therefore, it is essential for them to have symptom management strategies to cope with heartburn. The researcher studied on the strategies suitable and safe for both mothers and fetus to help them deal with heartburn. The strategies focused on the cooperation between the nurses and pregnant women suffering from heartburn to help resolve unpleasant symptom. The nurses need to educate patients and encourage them to modify their lifestyles and diets to reduce risk factors leading to symptom. In addition, the nurses had to encourage them to follow the advice and provide them with moral support to make sure that they were able to manage with heartburn effectively.

Outcomes

Outcomes are result indicators stating the quality and the effectiveness of symptom management. The outcomes of symptom management can be evaluated from eight indicators including: 1) symptom status, 2) functional status, 3) self-care, 4) costs, 5) quality of life, 6) morbidity and co-morbidity, 7) mortality, and 8) emotional status. In this study, the researcher used strategies included in the program developed to management heartburn in pregnant women. The expected outcomes focused on symptom statuses which are frequency and severity of heartburn.

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The periods of assessment were determined by the stability of symptom which required continuous management. After the symptom management was successful, the body would resume normal. Therefore, the constant practice was very crucial for patients to control the prospective symptom (Dodd et al., 2001). As a result, it was apparent that support and reinforcement of the nurses and the medical staff resulted to the excellent outcome of symptom management.

According to the symptom management model of Dodd et al. (2001), three basic factors apart from the three major concepts influence symptom management. These three basic factors are personal factor, health/illness factor, and environmental factor. Details of three basic factors are described as follow:

1. Personal factor are information regard to physical, psychological, emotional, social, and developmental status of a person. These factors include age, gender, race, personality, lifestyles, socioeconomic status, family background, religion, culture, and developmental change. Review of literature revealed that the more gestational age become, the more frequent and severe of the symptom found (Khresheh, 2011). Heartburn in pregnancy often occurred in Caucasian women comparing to the African women, 79 percent and 9 percent respectively due to their dietary and kind of food. Moreover, the Caucasian women tend to consume fatty food, drinking coffee and smoking cigarette which trigger relaxation in lower esophageal sphincter and results in heartburn. In addition, heartburn is related to lifestyles and meals, the symptom often occurred after dinner or in pregnant women who ate large amount of food, suddenly lied down or change position (Naumann et al., 2012; Richter, 2005)

2. Health/illness factors are basic factors related to health conditions, disease, deformity, or injury of an individual which affects symptom management. Review of literature revealed that risk factors such as over Body Mass Index (BMI) before pregnancy and over weight gain during pregnancy were related to the frequency and severity of heartburn in pregnant women (Jacobson, Somers, Fuchs, Kelly, & Camargo, 2006; Nandurkar, Locke III, Fett, Zinmeister, Cameron, & Talley, 2004).

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3. Environmental factors are factors related to living conditions and working conditions of an individual. Marital relationship, relationship with health

care personnel, social support, culture, beliefs and rituals of pregnant women and families are considered as environmental factors affect symptom management.

However, there is no report about the relationship of environmental factors and the occurrence of heartburn in pregnancy.

In this study, the researcher used the symptom management model of Dodd et al. (2001) as conceptual framework of this study and developed a heartburn symptom management program which was suitable and safe for mothers and fetus to reduce the frequency and the severity of heartburn in pregnancy and to provide pregnant women with effective symptom management strategies to control symptom experiences and improve outcomes. The procedures of the program included the assessment on symptom experiences of each pregnant woman before giving them advice about symptom management strategies and the investigation on heartburn perception, heartburn evaluation and heartburn response to have the common understanding between the nurses and the pregnant women. Also, it was important to be aware of the necessity of heartburn management, so it was required to evaluate symptom experience before operating the treatment according to the symptom management strategies. After that, the nurses giving instruction about causes, contributing factors, risk factors, and effects of the symptom, and followed by strategies used. The strategies introduced focused on lifestyles and dietary modification, continuous practice according to the booklet pregnant women received to review at home, and the follow-up and motivating and encouraging by phone was done to ensure continuously practice on strategies introduced once a week. Outcome of symptom management was evaluated by assessing the symptom statuses, which were the frequency and severity of heartburn. The effectiveness of heartburn management program was evaluated at the end of the program, which was four weeks after the program was started. The conceptual framework of this study was illustrated in figure 1.1.

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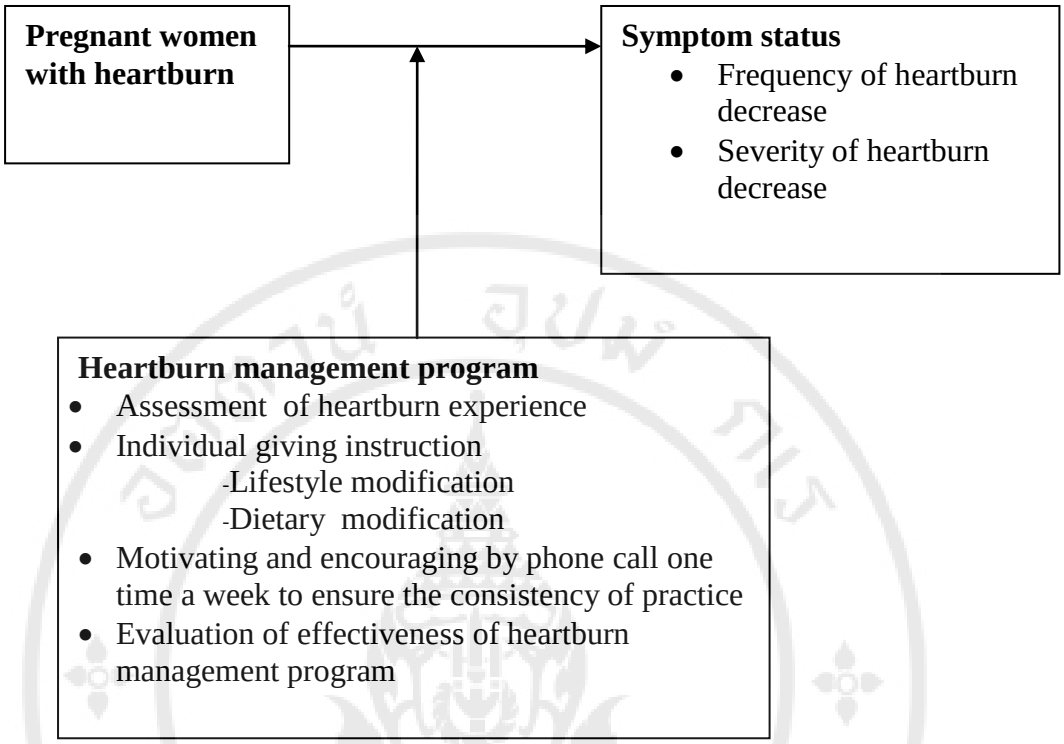

Figure 1.1 Conceptual framework of this study

Research Objectives

The objective of this study was to study the effect of heartburn management program on frequency and severity of heartburn in pregnant women.

Research Question

Could the heartburn management program decrease frequency and severity of heartburn in pregnant women?

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Research Hypotheses

The pregnant women with heartburn who received conventional health education program combined with heartburn management program had less frequency and severity of heartburn than those who received only conventional health education program.

Scope of the study

This quasi-experimental research was conducted in pregnant women who experience heartburn. These women came to prenatal clinic at Ramathibodi hospital, Bangkok, Thailand during January 2015 to May 2015.

Expected outcome and benefits

1. Nursing service. Results of the study can be used as guideline for nurse-midwives and health care team members in providing care for the pregnant women who experience heartburn.

2. Nursing education. Knowledge derived from this study can be utilized to develop nursing instruction in school of nursing, in regard to effective care for pregnant women with heartburn.

3. Nursing research. Results of the study can be used as guideline for further research and develop other effective program suitable for pregnant women with heartburn.

Definition of Terms

Heartburn management program is the nursing intervention program developed by the researcher, based on symptom management model of Dodd et al. (2001) combine with review of literature. The program composed of 1) assessment of heartburn experience; 2) verbal instruction using instruction CD by researcher about

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causes, aggravating factors, and strategies to alleviate heartburn focusing on lifestyle and dietary modification; 3) giving booklet of "Management of heartburn during pregnancy" to review at home; 4) explaining self-record of frequency and severity of heartburn; and 5) motivating and encouraging by phone call to ensure the consistency of practice to reduce heartburn. The program was individually introduced to the pregnant women who experienced heartburn at least one time per week and were in 24-32 week of gestation. Evaluation of effectiveness of the program was done at 4 weeks after the program was initiated.

Frequency of heartburn is the number of days per week which heartburn occurred. The frequency of heartburn was assessed by questionnaire developed by the researcher based on review of literature. The more number of days per week indicated that the pregnant woman had more frequency of heartburn

Severity of heartburn is the perception of pregnant women regard to the degree of interference of heartburn to normal daily activities. The severity of heartburn was assessed by questionnaire developed by the researcher based on review of literature. High score indicated that the pregnant woman had more severe heartburn.

Conventional health education program is group instruction routinely giving by staff nurse to pregnant women. The contents in the program are self-care during pregnancy, for instance dietary intake, sleep, rest, exercise, and so forth.

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CHAPTER II
LITERATURE REVIEW

This quasi-experimental research aimed to determine the effect of heartburn management program on frequency and severity of heartburn in pregnant women. The literature review is presented in the following topic:

Heartburn in pregnancy

Evaluation of heartburn

Theory of Symptom Management

Heartburn management strategies

Development of heartburn management program

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Heartburn in Pregnancy

Definition of Heartburn in Pregnancy

The researcher gathered the meanings of heartburn in pregnancy, as follows:

Heartburn is a painful burning sensation in esophagus due to gastro-esophageal reflux, then the gastric content coming back into esophagus (Jones, 2002). Heartburn is a painful burning sensation in the upper part of digestive tract resulted from gastro-esophageal reflux where some acid and gastric content coming back to esophagus causing pregnant women to encounter with an unpleasant symptom (Neilson, 2008).

Heartburn in pregnancy is the pain occurring from xiphoid process to the throat, belching of acid, bile or some gastric content into the esophagus. The symptom is not mainly caused by a gastrointestinal system, but it is resulted from the increase of progesterone during pregnancy (Audu & Mustapha, 2006).

Heartburn in pregnancy is the pain occurring from xiphoid process to throat which belch the bitter content from stomach to gullet (Dall' Alba, Fornari, Krahe, Callegari-Jacques, & Silva de Barros, 2010).

Heartburn in pregnancy is an unpleasant symptom occurring during pregnancy. It caused by hormonal changes and uterine enlargement. The pregnant women will face a painful burning sensation in chest and suffer from gastro-esophageal reflux, especially after meals (Richter, 2005).

In this study, the researcher defines heartburn in pregnancy as an unpleasant symptom characterized by a painful burning sensation in esophagus and sub-sternal regions, belching acid and bile, reflux of gastric to the esophagus. The symptom resulted from the changes in hormones and uterus during pregnancy. In addition, the pregnant women have never been diagnosed to have gastro-esophageal reflux disease or esophagitis before pregnancy.

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Symptoms of Heartburn in Pregnancy

Heartburn in pregnancy is one of the unpleasant symptoms that pregnant women always encounter with. The symptom of heartburn is characterized by a painful burning sensation around sub-sternal area due to reflux of gastric contents (Audu & Mustapha, 2006; Jungsa-nga, 2012; Nagler & Spiro, 1961). The study revealed that pregnant women begin to note symptoms of heartburn around the fifth month of pregnancy and the severity and frequency tend to increase as pregnancy progress (Richter, 2003). The symptoms generally occur in the short period of time and are involved with meals. The severity is from feeling uncomfortable to so unbearable that makes a pregnant woman cannot eat or rest (Monti, 2007; Neilson, 2008; Richter, 2003).

Causes and Factors Leading to Heartburn in Pregnancy

The major causes of heartburn in pregnancy are related to the changes during pregnancy. The literature review showed that the changes are concerning with two factors, including hormonal factor (endocrine changes) and mechanical factor (uterine changes).

1. Endocrine changes

The endocrine changes during pregnancy are evidenced by the increase level of progesterone and estrogen during pregnancy, which leads to LES relaxation and reflux of gastric content, finally causes pregnant women suffer from heartburn (Monti, 2007). Progesterone is a steroid hormone produced by corpus luteum during the first 10 weeks of pregnancy, and after that it will be produced by placenta. The amount of progesterone will increase and remain throughout pregnancy. The level of progesterone will reach up to 100-200 ng/ml by near term (Kumar and Magon, 2012). Findings from several studies revealed that the changes of the amount of progesterone and estrogen are related with the lower esophageal sphincter (LES) (Lind et al., 1968; Nagler & Spiro, 1961). Following the study on symptoms of heartburn in pregnancy by means of measuring LES pressure, basal gastric pH, fasting plasma gastrin, and plasma concentrations of estrone, estradiol, and progesterone in pregnant women at 12, 24, and 36 weeks of gestation and again at 1 to 4 weeks postpartum, it was found that basal gastric pH during pregnancy is higher than that the

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postpartum period but the LES pressure during pregnancy is lower than the postpartum period. The study also found that at the end of second trimester or at 24 weeks of gestation the strength of LES reduces around 33-50%, reaching a nadir at 36 weeks. However, LES pressure will return to normal within 1-4 weeks postpartum (Van Theil et al., 1977). Although progesterone is the main factor causing LES relaxing, estrogen also leads pregnant women to encounter with this symptom according to the result of study in animals on the impact of progesterone and estrogen on the mechanism of LES during pregnancy. Steroid hormone was injected into animals to make them have the similar conditions to pregnancy, it is found that a significant decreased in LES pressure was found in an experimental group ($p<.05$). However, there is no change in a control group (Schulze & Christensen, 1977). Results of the study was consistent with another experiment in animals which revealed that 17 beta-estradiol and progesterone significance decrease LES pressure ($p<.01$). Nevertheless, it is claimed that testosterone did not have an effect on LES relaxing (Fisher, Roberts, Grabowski, & Cohen, 1978). In addition, it is also consistent with the study in humans which showed that the LES pressure was significantly decreased in women who took birth-control pills such as progestin agent, dimethisterone and ethinyl estradiol ($p<.01$) (Van Thiel, Gavaler, & Stremple, 1976).

Not only hormones result in LES relaxation, it also influences the motility of small intestine and delays gastric empty time, which increases heartburn in pregnancy (Ali & Egan, 2007; Richter, 2005).

2. Uterine changes

The uterine changes during pregnancy are resulted from estrogen which increases the number and sizes of uterine muscle cells making uterus enlarge. The enlargement of uterus increases the intra-abdominal pressure and disturbs organs nearby, especially stomach which leads to heartburn and gastro-esophageal reflux. However, this theory still has limited evidence (Ali & Egan, 2007; Monti, 2007; Richter, 2005). Spence, Moir, and Finlay (1967) had studied and supported that the expansion of uterus led to the increase of abdominal pressure and press stomach and resulted in gastro-esophageal reflux. However, this is different from the findings of the study conducted by Van Thiel and Wald (1981) which

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disclosed that when the pressure in abdominal cavity increased, the LES pressure also became higher and was not the cause of heartburn.

According to the literature reviewed, it is revealed that the major factors causing heartburn in pregnancy is hormonal change and uterine change during pregnancy, clearly occurring from the second trimester and becoming peak at the third trimester of pregnancy. In addition, not only do the physical changes during pregnancy increase the chance of heartburn in pregnancy, but it is also related with other factors that are unable to specify. The study also disclosed that frequency and severity of heartburn vary from person to person.

Factors related to heartburn in pregnancy

Factors related to heartburn in pregnancy can be categorized into personal factors and health/illness factors. Details of these two factors are:

1. Personal Factors

The personal factors which reported to have relationships with heartburn in pregnancy include ages, races, gestational ages, number of pregnancy, lifestyles, and dietary habits of pregnant women.

1.1 Ages

Knudsen and others (1995) found that the pregnant women with older age had more severity of heartburn than the pregnant women with younger age ($p<.016$). This is consistent with the study conducted by Marrero et al. (1992) which showed that maternal ages are contributed to heartburn in pregnancy with the statistical significance ($p<.05$). It could be explained that the pressure in esophagus becomes lower and the relaxation of LES becomes greater when advanced age (Ferriolli, Oliveira, Matsuda, Braga, & Dantas, 1998; Pali, Hungin, & Raghunath, 2004).

1.2 Races

Heartburn was found more often in the Caucasian pregnant women than the Nigerians pregnant women, with the rate of 78.8 percent and 9.8 percent respectively. The Caucasians tend to consume fatty food which leads to LES relaxing (Bassey, 1977). On the other hand, the study carried out by Marrero et

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al. (1992) and Naumann et al. (2012) revealed that there is no correlation between races and heartburn in pregnancy.

1.3 Gestational Ages

Following a literature search, the symptoms of heartburn increases along with gestational ages, resulting from hormonal changes as mentioned earlier which cause relaxing. The symptom mildly occurs in the first trimester, gradually increases in the second trimester which the strength of LES reduces around 33-50 percent, and peaks at 36 weeks of gestation (Van Thiel et al., 1977). In addition, the enlargement of uterus presses internal organs in abdominal cavity and increases the intra-abdominal pressure, causing the frequency and the severity of the symptom more increases in the third trimester of pregnancy (Audu & Mustapha, 2006; Monti, 2007; Richter, 2005). Marrero et al. (1992) conducted a study in 607 pregnant women and found that the frequency of heartburn significantly increased with the gestational age ($p<.0001$). The frequency of the symptom in the first trimester was 22 percent, and in the second and the third trimester were 39 percent and 72 percent, respectively. This is consistent with the study conducted by Naumann et al. (2012) which disclosed that the frequency of heartburn in each trimester was 42 percent, 68 percent, and 71.1 percent, respectively. In brief, the frequency and the severity of heartburn will appear more in the second and the third trimesters or after 26 weeks of gestation (Van Thiel et al., 1977).

1.4 Number of pregnancy

It is reported that there is the correlation between number of pregnancy and heartburn. The study carried out by Bor et al. (2007) revealed that the frequency of heartburn in women who have at least one time of delivery is 1.5 percent whereas as the frequency in those who have more than two times of delivery is 15.1 percent. Likewise, Marrero et al. (1992) and Naumann et al. (2012) found that multiparous women have a higher chance to suffer from heartburn than the primiparous women. In addition, if pregnant women experience heartburn in the first pregnancy, 17.7-36.1 percent of them will suffer from the symptom in the second pregnancy with the statistical significance at $p<.001$. However, there is no evidence to explain the correlation between number of pregnancy and heartburn. It is

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only reported that the multiparous women have a higher chance to encounter with heartburn than the primiparous women.

1.5 Lifestyles/behaviors

The lifestyles and behaviors which lead to heartburn include smoking, alcohol drinking, stress, bodily movement and sleep position (Kaltenbach, Crockett, & Gerson, 2006).

1.5.1 Smoking

Several studies found that smoking involved with heartburn in pregnancy with the statistical significance in both active smoking and secondhand smoking (Naumann et al., 2012; Oliver et al., 2011). It is also found that the frequency of heartburn in smokers is higher than that of non-smokers. The 24-hour esophageal pH monitoring revealed that esophagus of smokers has longer esophageal acid exposure time and LES pressure significantly decreased (Dua, Bardan, Ren, Sui, & Shaker, 1998; Kadakia, Kikendall, Maydonovitch, & Johnson, 1995; Nilsson, Johnsen, Ye, Hveem, & Lagergren, 2004; Schindlbeck, Heinrich, Dendorfer, Pace, & Muller-Lissner, 1987).

1.5.2 Alcohol drinking

A literature search indicated that alcohol drinking has the correlation with heartburn. The frequency of heartburn increased about 32 to 43 percent in pregnant women who drink alcohol and the risk of heartburn in this group of women was significantly 2.85-time higher than the women who do not drink alcohol (Oliver et al., 2011; Wang, Luo, Dong, Gong, & Tong, 2004). In addition, it is found that alcohol drinking increases acid secretion through gastrin stimulation and decreases esophageal pH. Moreover, it reduces LES pressure (Bujanda, 2000; Grande, Manterola, Ros, Lacima, & Pera, 1997; Rubinstein, Hauge, Sommer, & Mortensen, 1993).

1.5.3 Stress

Although stress is not directly the cause of heartburn but it is a stimulus factor increasing the severity of symptom. The pregnant women who had high level of stress tended to experience heartburn 36-64 percent more than the pregnant women who had low level of stress with a statistical significance (Bhatia & Tandon, 2005; Letsche, 2001; Naliboff, Mayer, Fass,

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Fitzgerald, Chang, Bolus et al., 2004). Nagler and Spiro (1961) interviewed the pregnant women suffering from heartburn and reported that the symptoms occurred when the pregnant women were in stressful conditions or under pressure.

1.5.4 Bodily movements and sleep positions

The literature review disclosed that bodily movements after meals and sleep positions influenced the symptom of heartburn. The study carried out by Oliver et al. (2011) found that 14 percent of the pregnant women with heartburn immediately lied down after meals. In addition, sleep positions had an effect on heartburn. The study revealed that dorsal position can lead to heartburn more than elevated head of bed (28 centimeters) and left lateral position. Moreover, the 24-hour esophageal pH monitoring showed that the esophageal acid exposure time significantly decreases while slept in upright position (Hamilton, Boisen, Yamamoto, Wagner, & Reichelderfer, 1988; Stanciu & Bennett, 1977). It was reported that a right lateral position can increase the frequency and severity of heartburn. However, there is no clear explanation for this phenomenon, but symptom periods, acid remains in esophagus, longer time of LES relaxing are significantly higher than those of a left lateral position (Katz, Just, & Castell, 1994; Van Herwaarden, Katzka, Smout, Samsom, Gideon, & Castell, 2000).

1.6 Dietary habits

According to the literature review, dietary habit is one of the main factors causing heartburn in pregnancy. It is found that types of food, amount of food in each meal, and eating behaviors are related with the symptoms (Oliver et al., 2011), as follows:

1.6.1 Types of Food

Results of the study indicated that certain kinds of food such as fatty food, spicy food, chocolate, citrus fruits and juices, coffee and caffeine and carbonated beverages have the correlation with heartburn in pregnancy.

1.6.1.1 Fatty Food

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Following literature review, consuming of fatty food was a factor related to the severity of heartburn in pregnancy. The study carried out by El-Serag et al. (2005) showed that consuming high

cholesterol and fatty food significantly increases the chance to encounter with heartburn since this type of food will enhance LES relaxation. Result of the study was consistent with the study of Dall'Alba et al. (2010) who conducted the study in 89 pregnant women with gestational ages at 30 to 38 weeks. The results showed that eating polyunsaturated fatty food leads to heartburn and gastro-esophageal reflux in pregnancy with the statistical significance. However, there is no correlation between saturated fatty food and heartburn. The examples of polyunsaturated fatty food are sesame, peanut, chestnut and almond. Moreover, Nebel and Castell (1973) found that fatty food significantly reduced the LES pressure. On the other hand, eating protein can help increase the LES pressure. In addition, consuming high fatty food could increase the higher chance of esophagus to expose to acid than eating low fatty food (Iwakiri, Kobayashi, Kotoyori, Yamada, Sugiura, & Nakagawa, 1996).

1.6.1.2 Spicy Food

It was reported that 36 percent of pregnant women with heartburn ate spicy food (Oliver et al., 2011). Likewise, Nebel, Fornes, and Castell (1976) surveyed the gastro-esophageal reflux in pregnancy and found 88 percent of the samples consumed spicy food. Another study found that the frequency of heartburn in the samples eating onions leads to the increase of esophageal acid exposure with the statistical significance (Allen, Mellow, Robinson, & Orr, 1990). It could be explained that spicy food aggravates action of acids in stomach which in turn reflux to esophagus. The acids can damage esophageal mucosa which leads to the more severity of heartburn.

1.6.1.3 Chocolates

According to literature reviewed, chocolates are involved with heartburn in pregnancy and the severity of symptoms, fourteen percent of the sample had this symptom after drinking chocolates (Oliver et al., 2011). However, there is limited evidence that chocolates affect pH values in esophagus and LES pressure. The study without control group in 9 samples by measuring LES pressure found that drinking chocolate at 120 ml resulting in the decrease of LES pressure with the statistical significance ($p<.01$) (Wright & Castell, 1975). A study by using 24-hour esophageal pH monitoring revealed that there was the significant increase of acid exposure time in the samples that drank chocolate

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comparing with those who drank dextrose with the same osmolality and caloric values (Murphy & Castell, 1988). The findings have supported that drinking chocolates involve with heartburn (Kaltenbach, Crockett, & Gerson, 2006).

1.6.1.4 Citrus Fruits and Juices

It is reported that citrus fruits and juices which contain high acid values led to heartburn in 14 to 72 percent of the sample in the study of Feldman and Barnett (1995) and Oliver et al. (2011). This is consistent with the study conducted by Price, Smithson, and Castell (1978) which measured acid sensitivity in esophagus of people who drank orange juices and tomato juices. The study found that pH values in esophagus were significantly high comparing with those of people who drank plain water although pH values of orange juices and tomato juices are adjusted to a pH of 7. However, this finding is contrast with the study of Cranley, Achkar, and Fleshler (1986) which revealed that the LES pressure did not decrease after drinking 250 ml orange juices. Currently, it still lacks evidence to support that citrus fruits and juices lead to heartburn.

1.6.1.5 Coffee and Caffeine

Coffee and caffeine is one of the factors contributing to heartburn; however, study about the effect of coffee and caffeine on heartburn is still controversial (Kaltenbach et al., 2006). The study conducted by Thomas, Steinbaugh, Fromkes, Mekhjian, and Caldwell (1980) in 20 participants showed that coffee decreased LES pressure significantly. This is consistent with the study conducted by Salmon, Fedail, Wurzner, Harvey, and Read (1981) in 10 participants which revealed that drinking coffee decreased LES pressure significantly. However, there are several studies which indicate that there is no correlation between coffee and heartburn. Also, it is found that after drinking coffee, there is no change in LES pressure and the esophagus acid exposure time (Brazer, Onken, Dalton, Smith, & Schiffman, 1995; Di Baise, 2003).

1.6.1.6 Carbonated Beverages

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Ramu and others (2011) conducted the study in 400 pregnant women on frequency and risk factors causing

heartburn in pregnancy. The results showed that heartburn occurred in pregnant women who preferred to drink carbonated beverages with the statistical significance ($p<.001$). This is consistent with the results of several studies that LES pressure significantly reduced in people drinking carbonated beverages comparing with people drinking plain water (Fass, Quan, O'Connor, Ervin, & Iber, 2005; Hamoui, Lord, Hagen, Theisen, DeMeester, & Crookes, 2006).

1.6.2 The amount of food and eating behaviors

In addition to types of food leading to heartburn, a literature search also indicated that the amount of food in each meal and eating behavior are also the causes of heartburn. For example, consuming the large amount of food in each meal will lead to LES relaxing casing gastro-esophageal reflux in 27 percent of the pregnant women participated in the study (Holloway, Hongo, Berger, & McCallum, 1985; Kaltenbach et al., 2006; Oliver et al., 2011). In addition, it is found that the period of each meal such as delayed dinner time, the interval of each meal, and immediately lie down have correlated with heartburn in 23 percent of the sample and eating in rush leads to the symptoms in 27 percent of the study sample (Oliver et al., 2011).

2. Health/Illness Factors

The theory of Dodd et al. (2001) claimed that risk factors, health conditions, diseases, deformity or injury result to symptom experience, symptom management strategies and the outcome of symptom management strategies. It was found that risk factors such as pre-pregnancy Body Mass Index (BMI) and weight gained during pregnancy are factors predisposing to heartburn in pregnancy. The study of Jacobson et al. (2006) in 10,545 women showed that women with high BMI tended to experience the higher severity of heartburn than those with lower BMI. In addition, the rate of heartburn will increases 2.8 percent in every 3.5 kg/ m^2 of BMI. This is consistent with the study conducted by Nandurkar et al. (2004) which found that 10 percent of women with BMI over 25 kg/ m^2 experienced heartburn whereas only 4 percent of women with BMI below 25 kg/ m^2 had this symptom. It could be explained that the higher BMI increases the more chance of heartburn presents, since it

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reduces LES pressure. However, the study conducted by Marrero et al. (1992) in 607 pregnant women did not find the correlation between BMI before pregnancy and weight gained during pregnancy and heartburn.

Based on review of literature, it can be conclude that there are several factors leading to heartburn in pregnancy. However, each pregnant woman may experience the symptom of heartburn differently due to personal factors and related factors aforementioned.

Impact of Heartburn in Pregnancy

Heartburn affects health, leads to discomfort, involves dietary and sleeping pattern of pregnant women. The symptom would decrease quality of life and capacity to perform daily activities (Monti, 2007; Naumann et al., 2012; Neilson, 2008; Suzuki et al., 1994). The study conducted by Suzuki et al. (1994) on sleep patterns of 169 Japanese pregnant women who received prenatal care at Sapporo Hospital, Japan found that the sample had sleep disturbance due to the present of heartburn, especially in the third trimester of pregnancy with the statistical significance. It was also reported that some women with severe heartburn faced with weight loss, dehydration and finally led to gastro-esophageal reflux disease and esophagitis if they were not properly treated (Neilson, 2008; Richter, 2005). Therefore, it is every important for pregnant women be knowledgeable about the symptom and receive advice for self-management when the symptom occurs.

Evaluation of heartburn in pregnancy

The major cause of heartburn in pregnancy is from the changes during pregnancy resulting to an unpleasant symptom which disturbs daily activities, dietary pattern, and sleep pattern of pregnant women. Each pregnant women perceives and response to the symptom differently. Therefore, data regards to heartburn always come from the women who experience the symptom. The basic methods used to evaluate heartburn are the interview and by using questionnaires (Dodd et al., 2001).

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Data regards to frequency and severity of heartburn can indicate the status of heartburn. The frequency is the number of days the symptoms occur. The high

frequency such as the symptom presents every day will impact the health of pregnant women. On the other hand, the severity of the symptoms is the perception of each individual about the degree which the symptoms disturbs body, mind and emotion. If the frequency and the severity are high, impact on maternal health and fetal health may occur (Bytzer, 2004). The evaluation of the frequency and the severity of heartburn can be made by interviews and questionnaires, as follows:

The symptom evaluation by using interviews

The interview can be used to assess heartburn in pregnancy. This method is beneficial because it allows the participant to describe the symptom experience. The interview can be a structured or non-structured interview. The open-ended question used in the non-structured interview would allow the pregnant women to describe their feelings and attitudes towards the symptom experienced (Wyrwich & Staebler, Tardino, 2004). Moreover, the interview can be used in single method or a combination with other methods. For instance, a study conducted by Nagler and Spiro (1961) on heartburn in the last trimester of pregnancy by monitoring the movement of esophagus and utilizing medical equipment. In order to receive information about symptom experiences of pregnant women to support results of the study, the researcher had added the additional interviews concerning period of symptoms, the frequency, the severity, factors stimulating the symptoms and the impact on health. The findings revealed that pregnant women underwent various symptom experiences. For example, some faced the symptoms after 24 weeks of gestation, while began to experience the symptom after 28 weeks of gestation. The periods of symptoms were uncertain it could occur in both the short and the long period of time. The frequency of the symptoms tended to relate to meals, immediately lying after eating, and being in stress condition. Sometimes severity of the symptom was unbearable for the pregnant women and made them could not rest or sleep. Some women had to take antacid, while some need to modify their diets and lifestyles. On the other hand, some women deliberately ignore the symptoms. As a result, interview is one of the suitable methods to evaluate the symptoms of heartburn in a short period of time, receive the information required and enquire other specific questions. More importantly, the

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interviewers can receive direct information from pregnant women. However, the interview requires listening skills, main point summary and interpretation.

In addition to the interview, the simple and popular method to evaluate symptoms of heartburn is by using questionnaires, details are described as follows:

The symptom evaluation by using questionnaires

A literature search revealed that there was no instrument questionnaire used to assess heartburn in pregnant women. However, the researcher found the Reflux Disease Questionnaire (RDQ) developed by Shaw et al. (2001) to evaluating reflux disease in primary hospitals (Shaw, Talley, Beebe, Rockwood, Carlsson, &Adlis et al., 2001). Originally, the RDQ was developed by survey, interview and group discussion in 25 patients suffering from reflux disease. The interview was carried out by researcher team, including physicians and scholars. The data then were analyzed and categorized into 22 groups of symptoms occurred in the last four weeks. The questionnaire developed consisted of 12 items regards to the severity and the period of burning and pain behind breastbone, acid taste in mouth, movement of materials upward from the stomach, burning and pain in the upper stomach, position when highest severity happened, causes and factors worsening the symptoms (dietary behaviors and sleeping positions), the methods to relieve the symptoms such as taking antacid or certain kinds of diet, the impact of the symptom on sleep, working and quality of life. The questionnaire was a Likert scale ranging from 1-5 and 1-7. After the questionnaire was undergone the assessment of research tools by means of factor analysis, ten items were eliminated, then left only 12 items in the questionnaire. The revised questionnaire was used to gather data regards the frequency, the severity and the period of symptoms. Validity of the questionnaire was ascertained, the Cronbach's alpha coefficient obtained was 0.80-0.85. Moreover, reliability of the instrument was assessed by means of test-retest method; the reliability coefficient of 0.80-0.88 was obtained. After that, the questionnaire has been widely used.

The RDQ has been used in pregnant women, for instance the study conducted by Malfertheiner et al. (Malfertheiner S., Malfertheiner M., Monkemuller, Roehl, Malfertheiner P., & Costa, 2009; Malfertheiner S., Malfertheiner M., Kropf, Costa, & Malfertheiner P., 2012) and the study carried out by Dall'Alba et al. (2010)

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had adapted and utilized RDQ in the samples who were pregnant women suffering from reflux disease to investigate the frequency and the severity of gastro-esophageal reflux disease in pregnancy. In their studies, the samples were asked to self-report about the frequency and the severity of the symptoms occurred. The levels of the severity was categorized into six level, which were none, very mild, mild, moderate, severe and very severe, and the levels of the frequency were classified into none, less than one time/ week, more than one time/ week, 2-3 times/ week, 4-5 times/ week and every day. The instrument could be used to evaluate acid reflux disease in terms of typical symptoms and atypical symptoms. However, it is not suitable for being used to evaluate heartburn in pregnancy because the symptom is not resulted from the abnormality of gastrointestinal system like acid reflux disease.

Junghard and Wiklund (2008) used the Gastrointestinal Symptom Rating Scale (GSRS) developed by Svenlund, Sjodin, and Dotevall (1988) to study heartburn in pregnancy. The GSRS is a 4-grade modified Likert scale questionnaire, consists of 15 items related to heartburn. However, it was found that GSRS could not separate the severity, the frequency, and the period of symptoms. Therefore, many researchers had used and separated the evaluation on the severity into several levels, such as 4 levels (none, mild, moderate and severe), 5 levels (none, mild, moderate, severe, very severe), 6 levels (none, very mild, mild, moderate, severe, and very severe), and 7 levels (none, very mild, mild, moderate, a little severe, severe and very severe) (Bytzer, 2004). After it had been used, analysis on the severity levels of heartburn showed that a 4-grade modified Likert scale questionnaire has the highest validity and reliability, while the rest has the similar levels. The 4-grade modified Likert scale offers the definition of severity which perceived by an individual and the threatening results, and the frequency is the number of days that the symptoms appear. The description of severity of symptoms are showed as follows: 0 point (none), 1 points (mild: awareness of symptom but easily tolerate), 2 points (moderate: discomfort sufficient to cause interference with normal activities and sleep) and 3 points (severe: incapacitating with inability to perform normal activities or sleep).

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The review of studies on method and instrument used to evaluate the frequency and the severity of heartburn showed that there is no tool suitable to use directly with pregnant women suffering from heartburn. Therefore, in this study the

researcher developed a questionnaire based on literature review to assess the frequency and the severity of heartburn in pregnancy, covering symptom experiences, symptom management strategies and symptom management outcomes following the symptom management model of Dodd et al. (2001).

Symptom Management Model

The researcher used the symptom management model of Dodd and others (2001) developed from Symptom Management Model of Larson et al. (1994) as conceptual framework of this study. Dodd et al. (2001) stated that symptom management is based on the experience and the capacity of each individual in managing symptoms and providing effective self-care. If individuals could not care themselves they would need assistance from nurses. Currently, the symptom management model of Dodd et al. (2001) has been widely utilized. The model emphasizes on the nursing domains including person domain, health and illness domain, and environment domain, as describe in the following:

Person domain includes personal characters, mind, society, physical appearance, all of which are the components affecting the perception and response to the symptom of each person.

Health and illness domain covers health conditions, risk factors, injuries and disabilities which are both directly and indirectly affect symptom experience, symptom management strategies and outcomes.

Environment domain is a factor causing the symptom. This domain includes physical environment (houses, workplaces and hospitals), social environment (social support and the relationship of people) and culture environment (faith, value, race, religion and tradition).

There are five assumptions in Symptom Management Model. These assumptions are:

1) The gold standard for the studying the symptoms is based on the perception of the individual experiencing the symptom and self-report.

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2) The individual may be at risk for the development of the symptom because of the impact of a context variable such as a work hazard.

Therefore, intervention strategies may be initiated before an individual experiences the symptom.

3) The nonverbal or dependent patients e.g., infants, post stroke aphasic persons may experience symptoms and the interpretation by the parent or caregiver is assumed to be accurate for purposes of intervening.

4) The management strategy may be targeted at the individual, a group, a family, or the work environment.

5) Symptom management is a dynamic process; that is, it is modified by individual outcomes and the influences of the nursing domains of person, health/illness, or environment.

The symptom management model of Dodd et al. (2001) includes three components: symptom experience, symptom management strategies and outcomes, all of which are related with each other. The details are shown in figure 2.1 as follows:

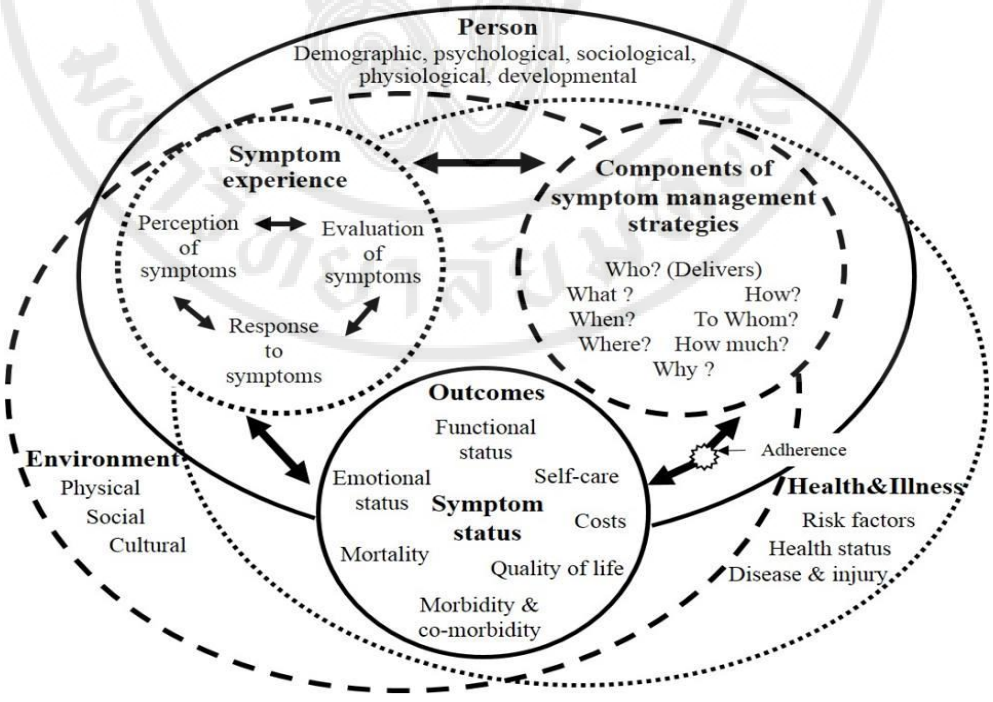

Figure 2.1 Symptom Management Model (Dodd et al., 2001)

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1. Symptom experience

Symptom experience includes perception of symptoms, evaluation of symptoms and response of symptoms.

1.1 Perception of symptoms

When there is some changes in body, people can perceive the occurring changes and lead them to observe their symptoms which are different from normal conditions. People can evaluate the symptoms by measuring the severity, causes, threat and impact on life. The perception of each person is various, based on personal factors and the occurring abnormality.

1.2 Evaluation of symptoms

It is the system which an individual used to manage the complexity of symptom experiences including severity, location, frequency, duration, impact on emotion conditions, and treat on life. An individual who suffer from a symptoms for a period of time tends to be able to explain the indication of the symptom better than those the one who never encounters with the symptom.

1.3 Response to symptoms

It is an expression of an individual when the symptom occurs. The response to symptoms might be shown by physiologic, psychological, sociocultural and behavioral expression such as bodily changes, nervousness, decreasing social activities or avoiding some foods.

In this research, symptom experience of pregnant women who encounter heartburn was assessed by gathering data regards to frequency and severity of the symptom.

2. Symptom management strategies

The objective of symptom management is to get rid of or slow down the symptoms by means of medical methods, care by specialists or nursing and self-care. The symptom management starts from the symptom evaluation by means of symptom perception and experiences. Normally, individuals tend to use the effective strategies which can help them get rid of or relieve an unpleasant symptom. However, if the strategies are ineffective, individuals will modify or use other strategies. The concerns

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in using symptom management strategies include what, when, where, why, how much, who, whom and how the strategies will be used.

In this study, the researcher used the care from specialists or nursing and self-care to manage heartburn in pregnancy. Following the symptom management model, if pregnant women cannot provide themself with suitable self-care for any reasons, the researcher as a nurse will provide them with knowledge and skills to promote their lifestyles and diet that can help prevent them from heartburn and to ensure that pregnant women possess sufficient knowledge to deal with heartburn effectively by themselves.

3. Outcomes

Outcomes are the results from symptom experience and symptom management. Dodd et al. (2001) assessed the outcomes of symptoms management strategies from eight indicators, including symptom status, functional status, self -care, costs, quality of life, morbidity and co-morbidity, mortality and emotional status. The outcomes of symptom management strategies for heartburn in pregnancy in this study were assessed from symptom status, which were frequency and severity of heartburn.

Research Related with Symptom Management Model

The symptom management model of Dodd et al. (2001) has been utilized in several nursing research to investigate the symptoms of patients and client. Some studies have used all three components of the model, while some have adopted some components to study various groups of samples in both descriptive research and quasi-experimental research. It was found that several researchers have applied the system management model of Dodd et al. (2001) to study unpleasant symptoms occurring in pregnant women, as follows:

Singkum (2005) conducted the study on the effect of an 8-week symptom management program on low back pain in pregnant women by using the symptom management model of Dodd et al. (2001) together with related literature review. The samples were 40 pregnant women suffering from low back pain caused by bodily changes during pregnancy. The severity levels were from moderate to very severe,

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evaluated by visual analog scale. The program included five steps: 1) evaluating symptom experiences of low back pain in pregnant women, which the pregnant women were requested to describe their symptom experience, severity levels, symptom response and outcome of symptom management, 2) giving advice to deal with low back pain, to reduce symptom experiences and to slow down negative outcomes by providing them with knowledge and skills of symptom management as well as support from the nurses in self-care, 3) enhancing skills in symptom management for low back pain in which pregnant women were required to follow the demonstration of the researchers, 4) practicing symptom management for low back pain at home to continually reduce the severity of symptoms and control the perspective symptoms, 5) Assessing the outcomes of symptom management for low back pain in terms of symptom status based on the theory of Dodd et al. (2001). The findings showed that the sample who received the low back pain management program had significantly lower severity levels of low back pain than those who did not receive the program ($p<.01$).

Jannarong (2007) carried out the study on the effect of 4-week low back pain management program on pain levels and disability of pregnant women by using the symptom management model of Dodd et al. (2001) and literature review to develop a symptom management program similar to the study conducted by Singkum (2005). The samples were 60 pregnant women suffering from low back pain caused by bodily changes during pregnancy. The severity levels are above level 2. The program took 4 weeks. There were certain steps including: evaluating of pain levels and disability before the program, equipping the samples with insight about symptoms, risk factors and causes of pain, offering symptom management strategies to reduce pain, instructing the appropriate movements in daily life and providing CD for exercising and reverse demonstration. In addition, the system management manual for low back pain during pregnancy was distributed to the sample to review and note the practice at home to stimulate and support the program. In addition, follow-up phone calls were made once a week. Results of the study revealed that the pregnant women who received the low back pain management program had significantly lower pain levels and disability than those who did not receive the program ($p<.001$).

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It is reported that heartburn in pregnancy affects dietary and sleep patterns and causes unpleasant symptoms. If pregnant women do not receive proper care, they might encounter with pregnancy complications (Monti, 2007; Naumann et al., 2012; Neilson, 2008; Suzuki et al., 1994). Khresheh (2011) conducted a study in 235 Jordanian pregnant women who experienced heartburn. The samples were both primigravida and multigravida. Results of the study indicated that the samples were aware that heartburn was a common symptom occurring during pregnancy. In addition, 7 percent of them did not use any strategy to deal with an unpleasant symptom, while 93 percent used various types of symptom management. Twelve percent of the sample took antacid such as cimetidine and ranitidine, whereas 85 percent of them used symptom management without medication use. When considering the details of each type of symptom management used by the samples, 14 percent of pregnant women modified their lifestyles such as eating a small amount of food in each meal but increasing the number of meals in each day, semi-sitting position and elevating head of bed. Most of the sample (98 percent) modified their diet such as avoiding foods and drinks leading to heartburn, e.g. spicy foods or citrus fruits, and use home remedies 34 percent. The home remedies used included drinking cold milk, drinking baking powder liquid, mixed herbal drinks, and eating cucumbers, lentil seeds or dry tea leaves. Although the symptom management which is medically recognized safety and suitability for pregnant women includes behavior and dietary modifications; however, there are some symptom managements that lack evidence to guarantee its safety and effectiveness such as indigenous medicine, herbal medicine and antacid. The physicians do not recommend pregnant women to take these types of medicine since they might have an impact on fetus (Monti, 2007; Neilson, 2008; Richter, 2005).

There is no study about heartburn in Thai pregnant women. Moreover, the literature review showed that the symptom management model of Dodd et al. (2001) has never been used in pregnant women who suffer from heartburn. Therefore, the researcher was interested in developing a heartburn management program for the pregnant women who experienced heartburn based on symptom management model of Dodd et al. (2001). The strategies used in the program are suitable and safe for

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pregnant women and could help the pregnant women alleviate this unpleasant symptom.

Heartburn management strategies in pregnancy

The literature review revealed that there are two strategies used to manage heartburn in pregnancy. These strategies are non-medication strategies and medication used. The non-medication strategies are lifestyle and dietary modifications. Details are as follow:

Lifestyle and Dietary Modifications

According to review of the literature, lifestyle and diet are predisposing factors of heartburn and increasing the severity of the symptoms. Therefore, lifestyle and dietary modifications are the most popular strategies used to alleviate the symptom. Lifestyle and dietary modifications used in pregnant women are similar to the patients who suffer from heartburn and gastro-esophageal reflux disease (Viriyautsahakul and Gonlachanvit, 2010). The study conducted by Ramu et al. (2011) showed that lifestyle and dietary modification could reduce the frequency and the severity of heartburn about 72.5 percent of the sample who experienced the symptom. Likewise, Khresheh (2011) found that 85 percent of pregnant women in the study did not use medicine to alleviate heartburn in pregnancy and 95 percent of them modified their lifestyles and diet by reducing or avoiding foods that stimulated the occurrence of symptom. Details of lifestyle, behavior and dietary modifications to reduce the frequency and the severity of heartburn in pregnancy are shown as follows:

Lifestyle Modification

Behavior and lifestyles modification which recognized as a method to reduce the severity of heartburn in pregnancy are

1. Avoid smoking

Although there is currently limited evidence to support that avoid smoking can prevent or relieve heartburn in pregnancy (Kaltenbach et al., 2006), the physicians still advise patients to stop smoking and avoid staying in

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smoking areas. Several studies on the correlation between smoking and heartburn and gastro-esophageal reflux showed that smoking reduces LES pressure, increases the frequency of gastro-esophageal reflux and causes acids to remain in esophagus longer due to the decreasing amount of saliva. These factors aggravate and increase the severity of symptom (Dua et al., 1998; Kadakia et al., 1995; Nilsson et al., 2004; Schindlbeck et al., 1987; Viriyautsahakul and Gonlachanvit, 2010). Moreover, smoking during pregnancy destroys the health of both maternal and fetus and might result in preterm birth, sudden infant death syndrome and increase the chance of miscarriage (Lin, Tsai, Chan, & Lin Yu, 2009). Therefore, it is necessary to advise the pregnant women who suffer from heartburn avoid smoking in order to promote their good health and fetuses' health.

2. Avoid drinking alcohol

Drinking alcohol stimulates heartburn and increases the severity of symptoms since the action of alcohol results to LES relaxing, reduces LES pressure and esophagus and stomach pressure and increases acid secretion through gastrin stimulation (Bujanda, 2000; Grande et al., 1997; Oliver, Davies, & Dettmar, 2011; Rubinstein et al., 1993; Wang et al., 2004). Moreover, it is reported that drinking the large amount of alcohol leads to fetal alcohol syndrome, intrauterine growth retardation, central nervous system problems and mental retardation (Lin et al., 2009). As a result, pregnant women should be advised to stop drinking alcohol to prevent and relieve heartburn although there is limited evidence that drinking alcohol has the correlation with heartburn (Kaltenbach et al., 2006).

3. Avoid lying down or bending suddenly after eating

The physicians always suggest patients avoiding sleeping or doing activities abruptly after eating, especially activities involved with bending down because during that time the stomach expands, leading to LES relaxing. Bending over or bowing will increase abdominal pressure stimulating the symptoms (Oliver et al., 2011; Ramu et al., 2011). Therefore, it is advised that after 2-3 hours of eating pregnant women should not lie down suddenly or bend down or bow to reduce factors leading to the symptoms (Viriyautsahakul and Gonlachanvit, 2010).

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4. Suitable sleep position

The study revealed that there is the correlation between sleep position and heartburn. In addition, it is found that elevated head of bed and left lateral position reduce the period of symptoms, decrease the esophageal acid exposure time and prevent the reflux of acids, bile and some gastric contents from refluxing to esophagus (Hamilton et al., 1988; Stanciu & Bennett, 1977). Therefore, the physicians and the nurses generally suggest pregnant women to elevate head of bed to at least 15-20 centimeter and sleeping in left lateral position to prevent and relieve heartburn and support circulatory system to uterus. The sleep positions that pregnant women should avoid are lying on back and lying on the stomach since these positions can press stomach, and acids in stomach can reflux to esophagus easily and lead to dyspnea (Jungsa-nga, 2012; Monti, 2007; Viriyautsahakul and Gonlachanvit, 2010).

5. Stress reduction

The high levels of stress can affect mental health of both mothers and fetus and increase the chance of preterm birth, low birth weight and other problems (Hobel, Goldstein, & Barrett, 2008). In addition, stress is a stimulus factor to increase the severity of heartburn (Bhatia & Tandon, 2005; Letsche, 2001; Naliboff et al., 2004). Therefore, it is crucial to advise the pregnant women to modify lifestyle in order to prevent tension and find relaxing activities such as doing favorite activities, reading, listening to music, practicing meditation and relaxing body. These activities help promote good health of pregnant women and fetus and reduce factors stimulating the symptoms of heartburn. However, there is still limited evidence to support the correlation between stress and heartburn in pregnancy (Kaltenbach et al., 2006).

Dietary modifications

The modification of diet, amount of food in each meal and dietary habits are important strategies to manage heartburn in pregnancy. A literature search showed that food is a main factor stimulating heartburn. Dietary modification can help reduce unpleasant symptoms of heartburn. The researcher gathered the suggestions related to dietary modification to avoid heartburn in pregnancy from several studies as follows:

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1. Pregnant women should avoid citrus fruits and juices. The patients tend to encounter with severe symptoms of heartburn after drinking juices such as lemonade, grape juice and tomato juice which increase acid values in esophagus despite base added to balance pH values of juices. Although, it is found the substances in fruit cause esophageal mucosa irritation, but there is no correlation between orange juice and heartburn (Cranley et al., 1986; Feldman & Barnett, 1995; Oliver et al., 2011; Price et al., 1978). There is limited evidence to support the effectiveness of avoiding citrus fruits and juices in relieving heartburn in pregnancy, however, the pregnant women should be advised to keep away from this type of food, e.g. tomato juice and grape juice to reduce stimulus factors leading to the symptom.

2. Avoid drinking carbonated beverages, tea and coffee is one of the strategies to reduce stimulus factors causing heartburn in pregnancy. Carbonated beverages such as soda not only increase gases in stomach leading to flatulence, belching and bloating but also significantly reduce LES pressure causing reflux of acids to esophagus (Fass et al., 2005; Hamoui et al., 2006). Moreover, caffeine drinks such as tea and coffee also can cause those symptoms (Salmon et al., 1981; Thomas et al., 1980). Therefore, the pregnant women should be advised to avoid carbonated beverages, tea and coffee even though there is limited evidence to support the correlation between avoiding these types of beverages and heartburn.

3. It is advised that pregnant women avoid spicy foods such as onions, papaya salad (Som Tam), spicy lemongrass soup (Tom Yam), chili sauce and other spicy foods because this type of foods are main stimulus factors increasing the esophageal acid exposure time and causing esophageal mucosa irritation leading to heartburn (Allen et al., 1990; Nebel et al., 1976).

4. It is suggested that pregnant women should not consume large amount of sweet food such as sweet dessert, syrups, sweet beverages and chocolate (Monti, 2007). It was reported that these foods increase the frequency of heartburn and reduce LES pressure (Kaltenbach et al., 2006; Murphy & Castell, 1988; Wright & Castell, 1975).

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5. It is important that pregnant women should avoid fatty foods such as fried foods, fat meat, vegetable oil, peanuts, onions and fast food (hamburger, steak, sandwich, pie, pizza, fried chicken, sausage, bacon, donut, cake and ice cream) because these foods are poorly digestible and increase gas in stomach. It is also found that fatty and indigestive foods stimulate LES to relax, cause body to create more acids and bile to digest fatty and indigestive foods. This leads to delayed gastric emptying time and results to heartburn and gastro-esophageal reflux (Dall'Alba et al., 2010; El-Serag et al., 2005; Iwakiri et al., 1996; Nebel & Castell, 1973). Moreover, it is reported that eating food rich of fibers can reduce the risk of heartburn. On the other hand, fatty food can cause obesity, diabetes mellitus, hypertension and hypercholesterolemia. Therefore, pregnant women should be advised to avoid fatty foods or eat in suitable amount.

6. It is suggested that pregnant women should not overeat since the hormonal changes during pregnancy affect the function of gastrointestinal system, i.e. the strength of LES declines. This causes the delayed movement of small intestine and the delayed gastric emptying time. In addition, the expansion of uterus presses stomach leading pregnant women to encounter with flatulence, indigestion, constipation and heartburn (Holloway et al., 1985; Kaltenbach et al., 2006; Oliver et al., 2011). Therefore, pregnant women should eat the suitable amount of food in each meal although they are supported to eat all five food groups and increase 300 calories per day to produce cells and tissues which promote the growth of fetus (Varney, Kriebs, & Gegor, 2004). As a result to prevent indigestion and gastro-esophageal reflux caused by overeating, the pregnant women should be advised to eat 4-6 meals per day but reducing the amount of food in each meal (Lopes, 2005).

7. It is advised that pregnant women should not have late dinners and avoid suppers. They should have dinner before 7.00 pm and eat before going to bed at least three hours which are the period of time allowing food to transmit from the stomach. This also can help prevent the reflux of acids, bile and some gastric content to esophagus (Jungsa-nga, 2012; Oliver et al., 2011)

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Heartburn management by means of lifestyle and dietary modifications can reduce the frequency and severity of symptom. However, there is

limited evidence to support the effectiveness of this strategy in pregnant women. There is only a study on the effectiveness of gastro-esophageal reflux symptom management (Lopes, 2005). The samples in this study were 6 women equipped with knowledge and insight about symptom management and given a manual of lifestyle and dietary modifications. The samples are required to follow the manual for 30 days, and comparison of the results before and after participating in the activities was made. However, there was no difference in statistical significance, but it was found that the severity of symptoms of 4 from 6 and the frequency of symptoms of 2 from 6 participants was lower (Lopes, 2005). So far, there is no study on the effectiveness of this strategy in Thailand.

Medication Use

The medication will be used to alleviate heartburn when lifestyle and dietary modification cannot control or relieve the occurring symptoms. It is suggested that pregnant women should be careful about medication used since there is no guarantee on the effectiveness and safety of fetus (Neilson, 2008). In case the symptoms become severe and pregnant women need to use antacid, it is crucial that they consult with obstetrician before using the medicines. They should not use any medication without prescription during pregnancy. Moreover, some antacids are quite hazardous; for instance, sodium bicarbonate might cause fluid overload and metabolic alkalosis in both mothers and fetus. In addition, it is reported that antacids inhibit iron absorption, so it is suggested that pregnant women should avoid taking antacid with the iron supplement during pregnancy. Antacid also affects gastric acid secretion and function of gastrointestinal system. Therefore, using antacid during pregnancy must be carefully considered about the benefits and the perspective risks (Ali & Egan, 2007; Gerson, 2012; Khresheh, 2011; Richter, 2005).

The literature review disclosed that there are several strategies used to reduce the frequency and the severity of heartburn in pregnancy such as providing knowledge about the symptom, lifestyle modification and suitable diet. In the present study, the researcher focuses only on the result of lifestyle and dietary modification to relieve symptoms of heartburn in pregnancy.

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The Development of Heartburn Management Program

The researcher developed the heartburn management program based on the symptom management model of Dodd et al. (2001) and related literature review. Within the program, symptom management strategies need cooperation between pregnant women and the nurse by utilizing the evidence that symptom management is based on the experience and the capacity of each individual in managing symptoms and providing effective self-care. Assistance from nurse is required when individuals could not provide themselves with self-care for any reasons (Dodd el al., 2001). The heartburn management program in this study includes three steps as follows:

1. Assessment of heartburn experience

The researcher assesses heartburn experience in pregnant women by using a questionnaires developed to gather data regarding frequency, severity, duration, symptom response, symptom management and the results of heartburn symptom management. The reason for assessing heartburn experience before implementing any activities is to make common understanding between pregnant women and the nurses, to help pregnant women realize and aware of the occurring symptoms, and to encourage them to cooperate and follow the suggestions provided. Dodd et al. (2001) pointed out that symptom experience is the perception of individuals to the changes of body. Individuals will evaluate the threat and the impact on their life from the frequency and the severity of the symptoms and respond to the changes leading to the observation on the abnormal symptoms. The symptom awareness helps increase effectiveness of symptom management. However, it will be more effective if the symptom perception is consistent with the symptom management. The foreign study revealed that 30-95 percent of pregnant women suffered from heartburn and the highest severity is in the third trimester of pregnancy (Audu & Mustapha, 2006; Khresheh, 2011; Knudsen et al., 1995; Naumann et al., 2012). Most of pregnant women realize that heartburn is a common symptom occurring as pregnancy progress and 85 percent of them ignore the symptoms or have a self-symptom management such as medication use, lifestyle and dietary modifications and indigenous treatment (Khresheh, 2011). Therefore, common understanding about symptom experience between pregnant women and the nurse is one of important strategies that can assist

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pregnant women receive the most effective heartburn symptom management (Dodd et al., 2001).

2. Giving individual instruction

The literature review showed that heartburn in pregnancy is caused by the changes during pregnancy and many related factors such as personal factors (age, gestational age, race, and parity), improper lifestyles (alcohol drinking, smoking and stress) and dietary habits (type of food, amount of food, and eating habits). In addition, it is found that giving advice about suitable lifestyle and dietary modifications can reduce the frequency and the severity of heartburn in pregnancy (Ali & Egan, 2007; Lopes, 2005; Monti, 2007; Ramu et al., 2011; Richter, 2005). The contents included in the instruction are causes of heartburn, risk factors and stimulating factors of heartburn, effects of heartburn, benefits and importance of lifestyle and dietary modifications for pregnant women suffering from heartburn. Dodd et al. (2001) emphasized that sufficient knowledge, skills, and supports can increase potentials and capacity in self-care of patients and provide them with proper self-symptom management. The knowledge offered aim to adjust symptom experience and help pregnant women to have self-symptom management in order to decrease the frequency and the severity of heartburn. In addition, heartburn symptom management is an activity to help reduce the acid exposure of esophagus, transfer food from stomach, decrease factors causing LES relaxing, prevent the damage of esophageal mucosa and diminish the frequency and the severity of heartburn (Dutta & Moayyedi, 2013). Although heartburn in pregnancy is caused by the changes in hormone and uterus, only some of pregnant women suffer from these changes. The symptoms tend to be found in pregnant women with reinforcing factors. The study conducted by Lopes (2005) revealed that lifestyle and dietary modifications can help reduce the frequency and the severity of heartburn.

The program developed equipped pregnant women suffering from heartburn with verbal individual instruction by the researcher. The instruction was 30 minutes long focusing on two ways communication and allowing for asking questions or concerns. The instruments used in instruction were lesson plan, CDs and computer-

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based media to illustrate symptoms, causes, precipitating factors and symptom management by proper lifestyle and dietary modifications in everyday life. The content put in the lesson plan was shown in Appendix A. After completion the instruction, pregnant women received a booklet of "heartburn management during pregnancy" to review at home. Moreover, there was an explanation about how to note the frequency and the severity of heartburn and they had to report the results after following the manual provided by the researcher. In addition, the women were assessed the outcomes after 4 weeks of participating in the program.

3. Motivating and encouraging by phone call

Motivating and encouraging by phone call was made to ensure the continuously of practice to reduce heartburn. The researcher made a 5 to 10 minutes phone call once a week to motivate and encourage pregnant women to practice heartburn management strategies. Evaluation of the program had been made at 4 week after the program was initiated.

A literature search revealed that heartburn in pregnancy is one of unpleasant symptoms which tend to occur in the last trimester of pregnancy. The main cause is from the changes of progesterone levels and the enlargement of uterus during pregnancy leading pregnant women to encounter with unpleasant symptoms, disturb dietary and sleep patterns, and reduce quality of life and capacity in doing daily activities. Beside bodily changes during pregnancy, there are other relating factors causing heartburn in pregnancy such as age, gestational age, parity, race, pre-pregnancy BMI, weight gain during pregnancy, dietary habits and lifestyles, which can be either controlled or uncontrolled. Moreover, it is reported that proper lifestyle and dietary modifications can help reduce the frequency of heartburn. However, there is no study on the symptoms of heartburn in Thailand. The information available is only from textbooks. Therefore, the researcher was interested in developing a nursing program to help pregnant women reduced the symptom of heartburn by utilizing the symptom management model of Dodd et al. (2001) and related literature review. The program was developed for pregnant women with gestational ages between 24 to 32 weeks when LES pressure decreases and expansion of uterus impacts the frequency and the severity of heartburn. The program included three steps: the evaluation on

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symptom experience of heartburn; the verbal instruction using the CD about causes, risk factors and effects, and the strategies to alleviate heartburn by means of lifestyle and dietary modifications; and motivating and encouraging continuously practice of strategies to reduce frequency and severity of heartburn. The effectiveness of the program had been evaluated at 4 weeks after the program was started.

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CHAPTER III
MATERIALS AND METHODS

Research design

This study was a quasi experimental research, two groups pretest-posttest design aimed to study the effect of heartburn management program on frequency and severity of heartburn in pregnant women. The research design of this study was illustrated in figure 3.1

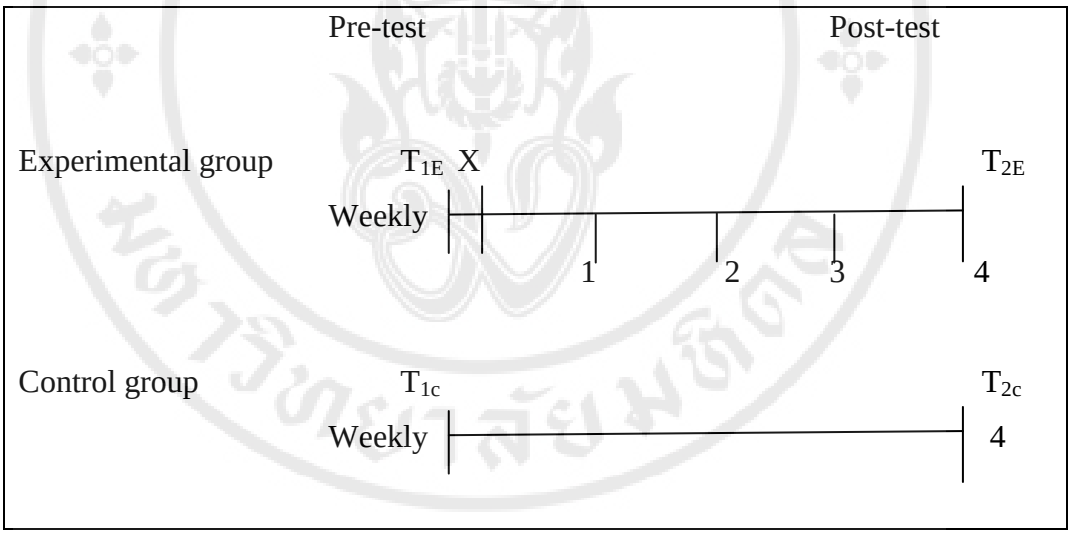

Figure 3.1 Research design of this study

T_{1E}: Tested about the frequency and severity of heartburn before entering the program in experimental group.

T_{2E}: Tested about the frequency and severity of heartburn after finishing the program in experimental group.

T_{1C}: Tested about the frequency and severity of heartburn at the beginning of program in control group.

T_{2C}: Tested about the frequency and severity of heartburn after finishing the program in control group.

X: Heartburn management program

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Population and Sampling

Population

The target population of this study was pregnant women who experienced heartburn.

Sample

The sample in this study consisted of 48 pregnant women who experienced heartburn. These women came to prenatal clinic at Ramathibodi hospital, Bangkok, during January 2015 to May 2015. The samples were selected by purposive sampling, based on the following inclusion criteria:

1) Had normal pregnancy and were in 24-32 weeks of gestation.

2) Experienced heartburn at least one time per week which the symptom was characterized by a painful burning sensation in esophagus and sub-sternal regions, belching acid and bile, reflux of gastric to the esophagus.

3) Had never encountered with heartburn before pregnancy or had been diagnosed with gastro-esophageal reflux disease, esophagitis, peptic ulcer, and duodenal ulcer.

4) Could verbal communicate, listen, read and write Thai language.

5) Were willing to participate in the study

The exclusion criteria were as follows:

1) The samples had pregnancy complications or severe heartburn that needed to take medicine or were diagnosed with gastro-esophageal reflux disease after entering the program.

2) The samples did not complete the 4-week- heartburn management programs.

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3) The samples took antacids, herbal medicine or utilized other strategies by themselves to alleviate heartburn.

4) The samples withdrew from the study for any reasons.

Sample Sizes

Since there was no sample size found in both domestic and foreign study related with this research to determine the effect size; therefore, the researcher determined the sample size by means of the criteria or population estimates. The criteria used percentage to determine sample sizes as follows (Srisa-ard, 1992):

15-30 percent of the samples should be considered in case the population was in hundreds.

10-15 percent of samples should be considered in case the population was in thousands.

5-10 percent of samples should be considered in case the population was in ten thousands.

1-5 percent of samples should be considered in case the population was in hundreds of thousands.

Prior to the study, the researcher surveyed and collected data from pregnant women at prenatal clinic, Ramathibodi Hospital, Mahidol University to determine the specific population. It was found that there were, on average, 300 to 500 pregnant women attending the services per month. In addition, 30 percent or 90 to 105 pregnant women were in the second trimester of pregnancy and suffered from heartburn. Based on the criteria, the population size was in the hundreds; therefore, at least 25 percent of the samples were taken into account in this study (Akakul, 2000). Finally, the total number of 48 pregnant women was recruited in the study, divided into two groups, the control group and the experimental group. Each group contained 24 pregnant women.

Research Setting

The setting of this research was at prenatal clinic, Ramathibodi Hospital, Mahidol University. The operating hours for normal pregnancy were on Monday, Wednesday and Friday from 08.00-12.00 AM. The nursing services provided for pregnant women in the second trimester included weighting, monitoring blood pressure, group instruction for initiation of breastfeeding, childbirth preparation and parenting. The pregnant women will receive physical examination and abdominal

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examination by an obstetrician or registered nurses. An appointment for next antenatal visit is based on weeks of gestation of the pregnant women. Usually, the schedule of two to four weeks is made during second trimester of pregnancy and every week after 36 weeks of gestation. However, in case of pregnancy complications, the frequency of appointment tended to increase according to the symptoms. In this study, the researcher had collected the data and provided heartburn management programs individually in a counseling room of prenatal clinic, which was private and separated from other activities of the clinic.

Research instruments

Research instruments used in this study consisted of two parts: the instruments for implementing the study and the instruments for data collection as the following:

1. Instruments for implementing the study

Instruments for implementing the study was heartburn management program developed by the researcher based on the symptom management model of Dodd et al. (2001) and related literature review. Components of the program included 1) assessment of heartburn experience; 2) verbal instruction using instruction CD by the researcher; and 3) motivating and encouraging by phone call to ensure the consistency of practice to reduce heartburn. The research instruments were described as follows:

1.1 Lesson plan for heartburn in pregnancy (Appendix A) was utilized as guidance for pregnant women in an experimental group. The content covered causes of heartburn, precipitating factors and symptom management strategies to reduce frequency and severity of symptoms by modifying behaviors, lifestyles and diet.

1.2 Instruction CD (Appendix B) was used to provide the knowledge to pregnant women in an experimental group; contents in the CD were congruent with the lesson plan, including the insight about symptoms of heartburn and proper lifestyle and dietary modification. The contents were retrieved from textbooks,

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journals, the internet and photographs which related to the lesson plan. The time used in each instruction was around 30 minutes.

1.3 Booklet of "heartburn management during pregnancy" (Appendix C) was a printed matter to offer knowledge about appropriate lifestyle and dietary modification to help pregnant women reduce frequency and severity of the symptom. The contents put in the booklet were similar to that in CDs which pregnant women were able to review and practice at home. The researcher had followed up, motivated and encouraged pregnant women to practice consistently at home by making a phone call once a week; each phone call was around 5-10 minutes to provide them with encouragement and assistance in case they had queries or problems.

Quality of the Instruments

Content validity

The lesson plan, the instruction CD, and the booklet were reviewed by a panel of three experts: two instructors in midwifery and one registered nurse in prenatal clinic (Appendix G) for content validity. The researcher revised the instruments according to experts' suggestions and tried out with three pregnant women who had the same characteristics as the sample. After trying out, the instruments were refined for better understanding and more readable before using them with the pregnant women in the study.

2. Instruments for Data Collection

The instruments used to collect data in this research were as follows:

2.1 Demographic Data Questionnaire (Appendix D) was developed by the researcher to collect data from pregnant women in terms of age, occupation, education level, family monthly income, number of pregnancy, gestational age, body mass index (BMI) before pregnancy, maternal weight gain during pregnancy and telephone number.

2.2 Heartburn Experience Questionnaire (Appendix E) was developed by the researcher based on the symptom management model of Dodd et al. (2001) to assess the pregnant women's perception of heartburn, evaluation of heartburn, and responses to heartburn. The questionnaire covered eight topics

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including: 1) gestational ages when the symptom occurred, 2) symptom description, 3) period of the symptom, 4) duration of the symptom, 5) response to the symptom, 6) number of days per week that the symptom occurred, 7) severity of the symptom, and 8) symptom management strategies. The question no.1 was an open-ended question and the questions no.2, 3, 4, 5, 6, 7 and 8 were multiple-choice questions. The question no. 7 was the evaluation of the severity of the symptom which was rating as follows:

Mild: awareness of symptom but easily tolerate

Moderate: discomfort sufficient to cause interference with normal activities and sleep

Severe: unbearable, affect the ability to perform normal activities or sleep

2.3 Heartburn Recording Form (Appendix F) was developed by the researcher based on literature review, textbooks, and documents related with heartburn to evaluate the outcomes of the symptom management strategies. The heartburn recording form included frequency and severity of heartburn which requested the pregnant women to record symptoms occurring after the fourth week of participating in the program. The details were shown as follows:

2.3.1 Recording Form of Frequency of Heartburn

The pregnant women were requested to fill out the form weekly in terms of the number of the days in which symptoms occurred. The more number of days per week indicated that the pregnant woman had more frequency of heartburn. On the other hand, the lower number of days per week indicated that the pregnant woman had lower frequency.

2.3.2 Recording Form of Severity of Heartburn

The pregnant women were requested to rate the severity of symptom which affected their lifestyle and sleep pattern. The alternatives were 4-points scale rating from 0-3 with criterion scoring as:

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	Score
No symptom	0
Mild level (awareness of symptom but easily tolerate)	1
Moderate level (discomfort sufficient to cause interference with normal activities and sleep)	2
Severe level (incapacitating with inability to perform normal activities or sleep)	3

Quality of the instrument

Content Validity

Content validity of the questionnaires and the recording form were established by a panel of three exerts in midwifery; two instructors in midwifery and one registered nurse in prenatal clinic (Appendix G). The items included in the questionnaires were examined their congruity with the conceptual of heartburn. Moreover, the clarity and the readability of each item, the explicitly and the simplicity to complete the questionnaires were ascertained. Lastly, the researcher modified the items in the questionnaires based on the experts' suggestions. In this study, the content validity index (CVI) was calculated (Polit and Hungler, 1999); the CVI of the demographic data questionnaire and the heartburn experience questionnaire obtained were 0.85 and 0.87 respectively.

Protection of Human Subjects

This study was carried out after the approval of the Committee on Human Right related to Researcher Involving Human Subjects at Faculty of Medicine, Ramathibodi Hospital, Mahidol University was granted (Appendix J). The potential participants were approached and informed about the purpose of the study, the expected beneficial outcomes, and their rights to participate or withdraw from the study at any time without any impact on nursing services they receive. The subjects were ensured that the data received from this study will be analyzed and presented as

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group data. Furthermore, information regarding privacy of the subjects will be kept confidentially. Finally, the pregnant women who agreed to participate in the study were requested to sign the consent form (Appendix H).

Data Collection

After the researcher had prepared the heartburn management program, the interventions and data collection were as follows:

1. The formal letter from the Faculty of Graduate Studies, Mahidol University, was submitted to the Director of Ramathibodi Hospital to ask for permission to implement the study at prenatal clinic.

2. After getting the permission from the director, the researcher met with the Director of Nursing in Obstetric Division and head nurse of prenatal clinic, to inform them about the study's objective, the study procedures, and the data collection.

3. The sample groups of the pregnant women were selected based on the inclusion criteria.

4. The selected samples were assigned into two groups, the control group and the experimental group.

5. Data collection in the control group took place on Monday while data collection in the experimental group took place on Wednesday and Friday. The purposes of separating the samples were to prevent intermingling and discrimination. For equality, the control group and the experimental group were balancing in terms of number of pregnancy, gestational age, maternal age, frequency and severity of symptom, since the literature review disclosed that those factors were involved with heartburn in pregnancy.

The intervention activities with each group were as follows:

Control Group: Received conventional health education program. The interventions in the control group were composed of two steps as follows:

Step1. The researcher met with the pregnant women to introduce herself, explained the purpose and the benefits of the study, the research process, the length of time to complete the questionnaires, and the right to participate

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in the study. Finally, the pregnant women who were willing to participate in the study were asked to sign the consent form (Appendix H).

After recruitment, the first data collection took place. Data regard to personal characteristics: age, occupation, educational level, family monthly income, number of pregnancy, gestational age, body mass index (BMI) before pregnancy, maternal weight gain during pregnancy and telephone number; and heartburn experience were gathered. The time spent in this session was 5-10 minutes.

Step2. The researcher met the participants 4 weeks after the program was started. The second data collection took place using the heartburn recording form. Lastly, the researcher thanked the pregnant women for their cooperation in the study. The time spent in this session was 5-10 minutes.

Experimental Group: Received conventional health education program combined with the heartburn management program. The intervention in the experimental group consisted of four steps as follows:

Step1. The researcher met with the pregnant women. The details of intervention in this step were similar to the details in step 1 of the control group that was mentioned above.

Step2. The researcher gave individual instruction using instruction CD about the causes of heartburn, impacts of heartburn, strategies to alleviate heartburn, including lifestyles and dietary modification. After the instruction was ended, the researcher gave a booklet entitled "heartburn management during pregnancy" to the pregnant women to review at home. The explanation about self-record of frequency and severity of heartburn was introduced and the samples were scheduled an appointment in the next first to the third week to ask for the follow-up by phone call. The time spent in this session was around 30 minutes.

Step3. The researcher made a phone call to the pregnant women once a week to motivate and encourage them to regularly use strategies suggested in the program to alleviate heartburn. The time spent in each phone call was around 5-10 minutes.

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Step4. The researcher met with the pregnant women on the fourth week after the program was initiated. The participants were asked to return the self-record form of heartburn. The second data collection (post-test) took place using

the heartburn recording form. Finally, the researcher thanked the participants for their cooperation in the study. The time spent in this session was around 5-10 minutes.

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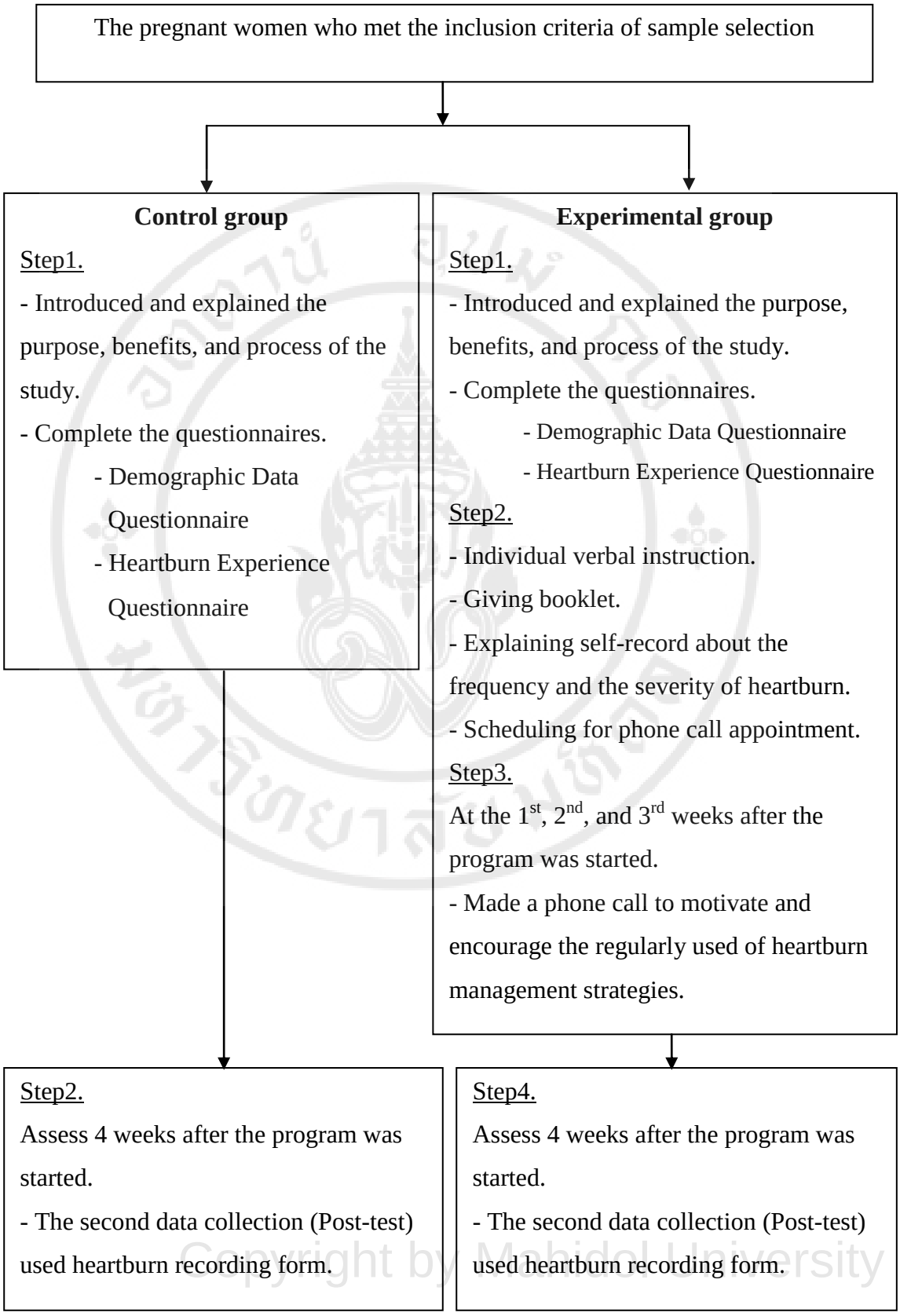

Figure 3.2 The process of data collection

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Data Analysis

Data was analyzed by using the computer program. The 95 percent confidence was set. The analyses were as follows:

1. Descriptive statistics: frequency, percentage, range, means, and standard deviation were used to describe the sample characteristics, the perception of heartburn, the evaluation of heartburn, and the response to heartburn.

2. The difference of sample characteristics between the control group and the experimental group was examined by using the chi-square test and the independent t-test.

3. After the program was completed, the researcher verified the distribution of the frequency and the severity of heartburn scores by using Kolmogorov-Smirnov test. The results disclosed that normal distribution of the scores was not found (Appendix K). The assumption in using the t-test was validated. Therefore, non-parametric statistics were used. The Wilcoxon signed ranks test was used to compare the pre-post test of the heartburn management program within group and the Mann-Whitney U Test was used to compare the effect of the heartburn management between the experimental group and the control group.

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CHAPTER IV
RESULTS

This research aimed to determine the effect of heartburn management program on frequency and severity of heartburn in pregnant women. Data was collected from January to May 2015. Results of the study are shown as follows:

Sample characteristics

In this study, the researcher collected the data from 30 pregnant women who were in the control group. However, six samples were eliminated since four of them were not able to participate in all steps of the research and the other two canceled the appointments. Therefore, there were 25 pregnant women in the experimental group but one of them was removed from the study because the researcher was unable to contact her on the phone each week. As a result, there were total 48 samples remained in the study, 24 in the control group and the other 24 in the experimental group.

The sample characteristics which contained continuous variables were compared by using independent t-test. Results of the study were shown in Table 4.1.

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Table 4.1: Comparison of sample characteristics between the control group and the experimental group in terms of age, gestational age, BMI before pregnancy and family monthly income (n=48)

Characteristics	Control Group (n=24)			Experimental Group (n=24)			t
	Min-max	Mean	SD	Min-max	Mean	SD	
Ages (year)	19-42	30.79	5.86	18-42	29.29	6.07	.87^{ns}
Gestational Ages (week)	25-32	27.92	2.02	24-32	27.75	2.34	.26^{ns}
BMI before pregnancy (kg/m^2)	16.52-24.90	20.30	2.25	16.59-25.10	21.58	2.28	-1.95^{ns}
Family monthly income (baht)	10,000-100,000	36,916	22,426	8,000-80,000	28,866	20,055	1.31^{ns}
	Median = 29,000	Mode = 50,000		Median = 25,000	Mode = 15,000		

$^{ns}p>.05$

Following Table 4.1, an average age of the experimental group was 29.29 years (SD = 6.07) whereas of the control group was 30.79 years (SD = 5.86). In addition, an average gestational age of the experimental group was 27.75 weeks (SD = 2.34) and of the control group was 27.97 weeks (SD = 2.02). Regarding the BMI before pregnancy, the experimental group had average BMI 21.58 kg/m^2 (SD = 2.28) and the control group had average BMI 20.30 (kg/m^2) (SD = 2.25). Lastly, a median family monthly income of the experimental group was 25,000 baht (Mean = 28,866, Mode = 15,000) and of the control group was 29,000 baht (Mean = 36,916, Mode = 50000). Upon analyzing the difference in terms of age, gestational age, BMI before pregnancy and family monthly income between the experimental group and the control group, it was found that they were not different at the significance level .05.

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Furthermore, the characteristics of the sample in the experimental group and control group which variables were in nominal scale were compared by using the chi-square test. Results of the test were shown in Table 4.2.

Table 4.2: Comparison of sample characteristics between the control group and the experimental group in terms of occupation, educational level, number of pregnancy, maternal weight gain during pregnancy (n=48)

Characteristics	Control group (n=24)		Experimental Group (n=24)		χ^2
	Number	Percentage	Number	percentage	
Occupation					2.34^{ns}
Unemployment	5	20.80	11	45.80	
Employment	19	79.20	13	54.20	
Educational level					6.80^{*}
Basic	8	33.30	18	75.00	
Bachelor's degree	16	66.70	6	25.00	
Number of pregnancy					$.086^{ns}$
Nulliparous	11	45.80	9	37.50	
Multiparous	13	54.20	15	62.50	
Maternal weight gain during pregnancy					$.00^{ns}$
Below normal	8	33.30	8	33.30	
Above normal	16	66.70	16	66.70	

$^{ns}p>.05$, $^{*}p<.05$

Following Table 4.2, 45.8 percent of the experimental group was unemployed, while only 20.8 percent of the control group was unemployed. Most of the samples in both groups worked outside the home, 79.2 percent in the control group and 54.2 percent in the experimental group. In addition, 75 percent of the experimental group held the basic education, whereas 66.7 percent of the control group received a bachelor's degree. Moreover, in terms of number of pregnancy, 37.5 percent of the samples in experimental group were nulliparous pregnant women, while 62.5 percent of them were multiparous pregnant women. Furthermore, 45.8 percent of

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the samples in control group were nulliparous pregnant women, while 54.2 percent of them were multiparous pregnant women. Regarding maternal weight gain during pregnancy, which depend on individual gestation age and BMI before pregnancy, about two-third (66.7 percent) of the sample in both groups had over weight gained. The difference of sample characteristics between the experimental group and the control group in terms of occupation, number of pregnancy and maternal weight gain was not found at the significance level .05. However, the educational level of the experimental group and the control group was different at the significance level .05.

Table 4.3: Heartburn experiences in an experimental group and a control group (n=48)

Characteristics	Control Group (n=24)		Experimental Group (n=24)	
	Number	Percentage	Number	Percentage
Perception of heartburn (More than one choice selection allowed)				
Normal symptom during pregnancy	22	91.70	18	75.00
Severity increasing with gestational ages	3	12.50	11	45.80
Treatment needed	3	12.50	4	16.70
Symptom disappearing after delivery	4	16.70	13	54.20
Gestational age when the symptom occurred				
3rd month	2	8.30	0	0
4th month	5	20.80	2	8.30
5th month	5	20.80	11	45.80
6th month	7	29.20	8	33.30
7th month	5	20.80	3	12.50

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Table 4.3: Heartburn experiences in an experimental group and a control group (n=48) (cont.)

Characteristics	Control Group (n=24)		Experimental Group (n=24)	
	Number	Percentage	Number	Percentage
Evaluation of heartburn				
(More than one choice selection allowed)				
Symptom description				
Painful burning sensation esophagus and substernal region	8	33.30	17	70.80
Acid or some gastric content coming back into esophagus	16	66.70	16	66.70
Belching	7	29.20	8	33.30
Acid mouthful	2	8.30	4	16.70
Bloating	11	45.80	9	37.50
Period of the symptom				
During the day	6	25.00	4	16.70
During the night	7	29.20	9	37.50
During the day and night	5	20.80	4	16.70
Uncertain	6	25.00	7	29.20
Duration of the symptom				
Less than 10 minutes	12	50.00	9	37.50
10 – 20 minutes	4	16.70	9	37.50
More than 20 – 30 minutes	5	20.80	2	8.30
More than 30 minutes–1 hour	3	12.50	4	16.70
Frequency of the symptom				
(days per week)				
1 day	3	12.50	5	20.80
2 day	9	37.50	3	12.50
3 day	8	33.30	5	20.80
4 day	3	12.50	2	8.30
5 day	1	4.20	2	8.30
6 day	0	0	0	0
7 day	0	0	7	29.20

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Table 4.3: Heartburn experiences in an experimental group and a control group (n=48) (cont.)

Characteristics	Control Group (n=24)		Experimental Group (n=24)	
	Number	Percentage	Number	Percentage
Severity of the symptom				
Mild	12	50.00	9	37.50
Moderate	12	50.00	15	62.50
Response to the symptom (More than one choice selection allowed)				
None	5	20.80	10	41.70
Dietary modification	12	50.00	10	41.70
Lifestyle modification	17	70.80	7	29.20

Following Table 4.3, the heartburn experiences of the samples in terms of perception of symptom revealed that 75 percent of the experimental group realized that heartburn was a normal unpleasant symptom during pregnancy and 45.8 percent found that the severity would be increasing along with gestational age. In addition, 16.7 percent needed proper treatment and 54.2 percent disclosed that the symptom would disappear after delivery. Likewise, 91.7 percent of the control group claimed that heartburn was a normal unpleasant symptom during pregnancy and 12.5 percent found that the severity would be increasing along with gestational age. Moreover, 12.5 percent of this group called for suitable treatment and 16.7 percent unveiled that the symptom would disappear after delivery. Furthermore, 45.8 percent of the experimental group started to encounter with the symptom at the fifth month of pregnancy, whereas 29.2 percent of the control group reported of having the symptom at the sixth month of pregnancy.

Regarding evaluation of the symptom, 70.8 percent of the experimental group suffered from painful burning sensation in esophagus and substernal region and 66.7 percent encountered with acid or some gastric content coming back into esophagus. Moreover, 33.3 percent faced with belching, 16.7 percent suffered from acid mouthful, and 37.5 encountered with bloating. In the control group, 33.3 percent

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suffered from painful burning sensation in esophagus and substernal region and 66.7 percent encountered with acid or some gastric content coming back into esophagus. Moreover, 29.2 percent faced with belching, 8.3 percent suffered from acid mouthful, and 45.8 percent encountered with bloating. Furthermore, majority of the sample in this study tended to encounter with heartburn at the night time, 37.5 percent in the experimental group and 29.2 percent in the control group respectively. In terms of duration of the symptom, 37.5 percent of the experimental group suffered from heartburn around 10-20 minutes, while 50 percent of the control group encountered with the symptom less than 10 minutes per time. Moreover, 29.5 percent of the experimental group faced with heartburn every day, whereas 37.5 percent of the control group suffered from heartburn around two days per week. For the perception of severity of heartburn, 37.5 percent of the experimental group suffered from the symptom in mild level and 62.5 percent in moderate level. Also, half of the sample in the control group encountered with heartburn in mild level and the other half in moderate level.

Considering response to the symptom, results of the study revealed that 29.2, 41.7 and 41.7 percent of the experimental group adopted the strategies to reduce heartburn by lifestyle modification, dietary modification and ignoring the symptoms, respectively. On the other hand, 70.8, 50 and 20.8 percent of the control group modified their lifestyles, dietary modification and ignored the symptoms, respectively.

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Results of hypotheses testing

Table 4.4: The frequency before entering the program and after finishing the program in the control group and the experimental group (n=48)

Number of days per week	Frequency of heartburn							
	Control Group (n=24)				Experimental Group (n=24)			
	Before the program		After the program		Before the program		After the program	
	Number	Percentage	Number	Percentage	Number	Percentage	Number	Percentage
0 day	0	0.00	4	16.70	0	0.00	12	50.00
1 day	3	12.50	9	37.5	5	20.80	7	29.20
2 day	9	37.50	7	29.2	3	12.50	3	12.50
3 day	8	33.30	2	8.30	5	20.80	2	8.30
4 day	3	12.50	0	0.00	2	8.30	0	0.00
5 day	1	4.20	2	8.30	2	8.30	0	0.00
6 day	0	0.00	0	0.00	0	0.00	0	0.00
7 day	0	0.00	0	0.00	7	29.20	0	0.00

Following Table 4.4, it was found that the frequency of heartburn before entering the program, Most of pregnant women in control group suffered from heartburn around two days per week and 12.5, 33.3, 12.5 and 4.2 percent of the control group face with heartburn around one day, three days, four days and five days per week, respectively. Moreover, the frequency of heartburn before entering the program in experimental group found that majority of pregnant women in this group suffered from heartburn every day, whereas 20.8, 12.5, 20.8, 8.3 and 8.3 percent of the experimental group face with heartburn around one day, two days, three days, four days and five days per week, respectively.

However, after finishing the program, found that the frequency of heartburn of the control group, most of pregnant women in this group suffered from heartburn only one day per week. In addition, the pregnant women in the experimental group were decrease of frequency of heartburn more than the pregnant women in control group. Also, half of the sample in experimental group had never symptom occurred after the program completely.

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Table 4.5: The severity of heartburn before entering the program and after finishing the program in the control group and the experimental group (n=48)

Symptom status	Severity of heartburn							
	Control Group (n=24)				Experimental Group (n=24)			
	Min-Max	Mean	SD	Median	Min-Max	Mean	SD	Median
Before the program	1-2	1.50	0.51	1.50	1-2	1.62	0.49	2.00
After the program	0-2	1.00	0.59	1.00	0-1	0.50	0.51	0.50

Following Table 4.5, it was found that before entering the program, the average scores of the severity of heartburn of the control group was 1.50 scores (SD = 0.51) (Median = 1.50) and the average scores of the severity of heartburn of the experimental group was 1.62 score (SD = 0.49) (Median = 2.00). However, after finishing the program, the scores of the severity of heartburn of the control group was 1.00 score (SD = 0.59) (Median = 1.00) and the scores of the severity of heartburn of the experimental group was 0.50 score (SD = 0.51) (Median = 0.50).

Table 4.6: Comparison of the frequency and the severity of heartburn in the experimental group and the control group from the beginning to the end of heartburn management program (n=48) (Wilcoxon signed ranks test)

Samples	Time evaluation	n	Z	p-value (one-tailed)
Control Group	Frequency of heartburn before entering the program – after finishing the program	24	2.73	.01
	Severity of heartburn before entering the program – after finishing the program	24	2.97	.00
Experimental Group	Frequency of heartburn before entering the program – after finishing the program	24	4.22	.00
	Severity of heartburn before entering the program – after finishing the program	24	4.21	.00

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Table 4.6 showed the results of the test on difference of median of the frequency and the severity of heartburn before and after the program completed in 48 samples. The results of data analysis revealed that the frequency of heartburn before and after the program in the control group was different at the significance level .05 ($z = 2.73$, $p < .05$) and the severity of heartburn was different at the significance level .05 ($z = 2.97$, $p < .05$).

Likewise, the frequency of heartburn before and after the program of the experimental group was different at the significance level .05 ($z = 4.22$, $p < .05$) and the severity of heartburn was different at the significance level .05 ($z = 4.21$, $p < .05$).

Based on the hypothesis "The frequency and severity of heartburn in pregnant women suffering from heartburn would be lower after participating in heartburn management program," after comparing the median of the frequency and the severity of heartburn in the experimental group before and after the program, it was found that the frequency and severity of heartburn after finishing the program was lower than before entering the program at the significance level .05. Therefore, this hypothesis was accepted.

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Table 4.7: Comparison of the frequency and the severity of heartburn in the experimental group and the control group from the beginning to the end of heartburn management program (n=48) (Mann-Whitney U Test)

Time evaluation	n	Mean Rank	Mann- Whitney U	
			Z	p-value (one-tailed)
Frequency of heartburn before entering the program in the			-1.69	.05
control group	24	21.17		
experimental group	24	27.83		
Total	48			
Frequency of heartburn after finishing the program in the			-2.43	.01
control group	24	29.21		
experimental group	24	19.79		
Total	48			
Severity of heartburn before entering the program in the			-0.86	.18
control group	24	23.00		
experimental group	24	26.00		
Total	48			
Severity of heartburn after finishing the program in the			-2.83	.00
control group	24	29.50		
experimental group	24	19.50		
Total	48			

Table 4.7 showed the results of the test on difference of median of the frequency and the severity of heartburn before and after the program was completed of the samples in this study, 24 samples in each group. Results of the study revealed that the frequency of heartburn before entering the program in the control group and the experimental group was different at the significance level .05 ($z = -1.69$, $p = .05$).

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Following the data analysis by using the frequency of heartburn before entering the program as covariate in ANCOVA, it was found that the frequency of heartburn before entering the program was not affected to the frequency of heartburn after finishing the program at the significance level .05 ($F_{1,45} = 3.05$, $p = .088$) shown in Appendix L. Therefore, the frequency of heartburn after finishing the program in both groups was different at the significance level .05 ($z = -2.43$, $p < .05$).

Regarding severity of heartburn, results of the study revealed that there was no statistical difference between the two groups before entering the program ($z = -0.86$, $p > .05$). However, the severity of heartburn after finishing the program in the control group and the experimental group was different at the significance level .05 ($z = -2.83$, $p < .05$).

Base on the hypothesis "The pregnant women with heartburn who received conventional health education program combined with heartburn management program had less frequency and severity of heartburn than those who received only conventional health education program," after comparing the median of the frequency and severity of heartburn between the experimental group and the control group, it was found that the frequency and severity of heartburn in the experimental group was lower than the control group at the significance level .05. Therefore, this hypothesis was accepted.

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CHAPTER V
DISCUSSION

This quasi experimental research aimed to determine the effect of heartburn management program on frequency and severity of heartburn in pregnant women. The samples were 48 pregnant women suffering from heartburn and received prenatal care at Ramathibodi Hospital, Bangkok. The samples were randomly selected by purposive sampling and categorized into two groups: 24 in the control group and the other 24 in the experimental group. The experimental group received conventional health education program and heartburn management program, whereas the control group received only conventional health education program. The findings can be discussed, as follows:

Sample characteristics

Results of data analysis revealed that characteristics of the samples in both groups were not statistically different.

The analysis on the sample characteristics in terms of occupation, educational level and family monthly income showed that most of pregnant women in both groups worked outside the home (79.2 percent in the control group and 54.2 percent in the experimental group). In addition, the average family monthly income between groups was not statistically different. The experimental group earned 28,866 baht per month and the control group earned 36,916 baht per month. However, the educational level in both groups was different. Majority of the sample in the experimental group held the basic education, whereas 66.7 percent of the control group received a bachelor's degree. Following the literature review, it was found no study indicating the correlation of educational level on heartburn in pregnancy.

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An average age in the control group was 30.79 years and the experimental group was 29.29 years. Most pregnant women aged more than 20 years suffered from

heartburn. Since the functioning of esophagus changed with its ages i.e. the frequency of LES relaxing tended to increased and the strength of esophagus contractility was decreased when people were older. As a result, older pregnant women had a higher chance to suffer from heartburn. (Ferriolli et al., 1998; Pali et al., 2004). This was consistent with the study conducted by Marrero et al. (1992) and the study carried out by Knudsen et al. (1995) which found that heartburn occurred in older pregnant women than in younger pregnant women with statistically significance ($p < .05$). Moreover, in terms of number of pregnancy, most of the samples in both groups were multiparous pregnant women (54.2 percent in the control group and 62.5 percent in the experimental group). This result was congruent with the research conducted by Marrero et al. (1992) and Naumann et al. (2012) which claimed that multiparous pregnant women tended to suffer from heartburn more than nulliparous pregnant women at significance level .05.

The average gestational age of the samples in both groups was not different. The average gestational age in the control group and the experimental group were 27.92 weeks and 27.75 weeks respectively, which were in the third trimester of pregnancy. The bodily changes during pregnancy apparently affected pregnant women i.e. the increasing influence of progesterone decreased the strength of LES. In addition, the expansion of uterus disturbs organs nearby, especially stomach. As a result, pregnant women in the third trimester tended to suffer from heartburn. It was reported that gestational age was a significant factor of heartburn in pregnancy. This was consistent with the study conducted by Marrero et al. (1992) which found that the frequency of heartburn would increase 39 percent in the second trimester and up to 72 percent in the third trimester. In addition, the research carried out by Naumann et al. (2012) revealed that the frequency of heartburn in each trimester was 42, 68 and 71.7 percent, respectively. Moreover, Van Thiel et al. (1977) disclosed that at the end of the second trimester, the strength of LES could be decreased at 33-50 percent, especially in the third trimester when LES loosened the most and its strength was reduced the most at 36 weeks of gestational age. Furthermore, the expansion of uterus with the increasing gestational age resulted to heartburn in the last trimester of pregnancy (Audu & Mustapha, 2006; Monti, 2007; Richter, 2005).

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In terms of BMI before pregnancy and maternal weight gain during pregnancy, BMI before pregnancy of the samples in both groups was not statistically different ($p > .05$). Average BMI before pregnancy in the experimental group and the control group was 21.58 kg/m^2 and 20.30 kg/m^2 respectively, which were in normal level. Likewise, maternal weight gain during pregnancy of the samples was not different with statistical significance. About 66.7 percent of the samples in both groups had over weight gained. In addition, it was found that the samples who suffered from heartburn tended to have over weight gained. According to literature, it was found that overweight and obesity were a risk factor causing heartburn in normal people and pregnant women (Jacobson et al., 2006). This was compatible with the study carried out by Jacobson et al. (2006) and Nandurkar et al. (2004) which claimed that pregnancy women with higher BMI had more risk to suffer from heartburn than those who had lower BMI. However, it was not congruent with the study conducted by Marrero et al. (1992) which found that there was no relationship between BMI before pregnancy and heartburn, and also found that there was no relationship between maternal weight gain during pregnancy and heartburn.

Heartburn experience

In terms of the perception of heartburn, it was found that most of the samples in both groups were aware of the bodily changes caused by heartburn. The symptom tended to start occurring when their gestational age was fifth to sixth month (79.1 percent and 50 percent, respectively). This was similar to the foreign study which reported that pregnant women firstly encountered with heartburn at the fifth month of pregnancy (Nagler & Spiro, 1961; Neilson, 2008; Richter, 2005). This confirmed that heartburn in pregnancy was caused by the changes in hormones and the expansion of uterus leading to the relaxing of LES at the end of the second trimester and LES relaxed the most in the third trimester of pregnancy (Spence, Moir, & Finlay, 1967; Van Thiel et al., 1977). In addition, most of the samples in both groups realized that heartburn was a common unpleasant symptom occurring during pregnancy (75 percent and 91.7 percent, respectively) and they were aware that the severity of heartburn was related with the increasing gestational age (45.8 percent and 12.5

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percent, respectively) and the symptom would disappear after delivery (54.2 percent and 16.7 percent, respectively). However, only the minority of the samples in both groups were aware that they needed treatment to manage with heartburn (16.7 percent and 12.5 percent, respectively). The findings showed that the majority of the samples had positive perception of heartburn in pregnancy, consistent with the study carried out by Khresheh (2011) which claimed that pregnant women did not report the occurring symptom of heartburn to health care providers. Eighty-five percent of the samples tolerated with heartburn and had their own strategies to deal with the symptom.

Perception of symptom was related with evaluation of symptom, response to symptom, and the selection of symptom management strategies (Dodd et al., 2001). This was consistent with the findings of this study in which the samples in both groups would evaluate the symptom upon perceiving the symptom by reporting the symptom occurred (description, frequency, severity, position of symptom and period of symptom). About seventy percent of the samples in the experimental group suffered from painful burning sensation in esophagus and substernal region and 66.7 percent encountered with acid or some gastric content coming back into esophagus. Moreover, 37.5, 33.3 and 16.7 percent suffered from bloating, belching and acid mouthful, respectively. Likewise, most of the samples in the control group also reported the occurring symptoms. About 66.7 percent encountered with acid or some gastric content coming back into esophagus and 45.8 percent faced with bloating. Moreover, 33.3, 29.2 and 8.3 percent suffered from painful burning sensation in esophagus and substernal region, belching and acid mouthful. Furthermore, it was reported that majority of the samples in both groups tended to encounter with heartburn during the night time, especially after dinner. In addition, 29.2 percent of the experimental group and 25 percent of the control group suffered from the symptoms at the uncertain time. In terms of duration of the symptom occurred, most of the samples suffered from heartburn in short period of time. Seventy-five percent in the experimental group suffered from heartburn around 5-20 minutes per time and the symptom occurred at least once a week to every day. About 37.5 percent in the experimental group suffered from the symptom in mild level and 62.5 percent in moderate level. In addition, half of the sample in the control group encountered with

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the symptom less than 10 minutes per time and suffered from heartburn around one to five days per week. Also, half of the sample in the control group encountered with heartburn in mild level and the other half in moderate level causing them to face with an unpleasant symptom. The heartburn evaluation of the samples in this study was consistent with several foreign studies which found that heartburn in pregnancy was characterized by a painful burning sensation in esophagus and substernal region, belching and acid mouthfuls due to acid or bile reflux as well as some gastric content coming back into esophagus (Audu & Mustapha, 2006; Nagler & Spiro, 1961; Richter, 2005). The symptom tended to occur in the short period and was involved with meals. The severity and frequency tended to increase along with gestational age.

The findings of this study revealed that most of pregnant women had positive perception of heartburn and evaluated heartburn that it was a temporarily unpleasant symptom which no special treatment was requested. As a result, 41.7 percent in the experimental group and 20.8 percent in the control group tended to ignore the symptom. In addition, pregnant women had their own strategies to deal with heartburn. For instance, 41.7 percent in the experimental group and 50 percent in the control group modified their diet such as avoiding spicy food, citrus fruits and juices and the large amount of food in each meal. Moreover, they modified their lifestyles such as sleeping in the position of elevating head of bed and avoiding sleeping immediately after the meal. This was consistent with the study on symptom management which Jordanian women used to cope with heartburn in pregnancy conducted by Khresheh (2011). The samples were aware that heartburn was a common symptom occurring during pregnancy. In addition, 7 percent of them did not adopt any symptom management to deal with an unpleasant symptom, while 93 percent utilized various types of symptom management. 12 percent took antacid, while 14 percent modified their lifestyles such as eating a small portion in each meal but increasing the number of meals in each day, sleeping in the sitting position and elevating head of bed. Ninety-eight percent modified their diet such as avoiding foods and drinks leading to heartburn, e.g. spicy or acid foods, while 34 percent used home remedies such as drinking ice milk when the symptom occurred, drinking baking powder, mixed herbal drinks, eating cucumbers, peanuts and dried tea leaves (Khresheh, 2011).

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Based on findings of the study, it was found that perception of symptom, evaluation of symptom and response to symptom were related but various from person to person, consistent with the theory of Dodd et al. (2001). The samples had positive perception of heartburn and realized that heartburn was a temporarily unpleasant symptom that required no special treatment. Therefore, most of pregnant women did not report heartburn to the health care provider.

Results of hypothesis testing

Hypothesis of the research was that the pregnant women with heartburn who received conventional health education program combined with heartburn management program had less frequency and severity of heartburn than those who received only conventional health education program.

The findings showed that the frequency and the severity of heartburn in the experimental group after finishing the program was lower than before entering the program at the significance level .05 ($z = 4.22$, $p < .05$ and $z = 4.21$, $p < .05$, respectively). Upon comparing the frequency and the severity of heartburn between the experimental group provided with conventional health education program and heartburn management program and the control group offered only conventional health education program, it was found that the frequency and the severity of heartburn in the experimental group were lower than the control group at significance level .05 ($z = -2.43$, $p < .05$ and $z = -2.83$, $p < .05$, respectively). The findings indicated that the heartburn management program was able to assist in reducing the frequency and the severity of heartburn in pregnancy. Therefore, this hypothesis was accepted.

The heartburn management program could reduce the frequency and the severity of heartburn in pregnancy was consistent with the theory of Dodd et al. (2001) stating that strategies to manage heartburn such as medical methods, care by specialists or nursing and self-care aimed to eliminate negative effects of symptom or to deviate the symptom. In this study, the researcher as a nurse developed the heartburn management program combined with care by specialists or nursing and self-care strategies of pregnant women. The program was related with the theory of Dodd

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et al. (2001) which claimed that an individual possessed potential in effective self-care. If not, they would be supported in terms of nursing which helped enhance their potential. In addition, the researcher assessed heartburn experience of each pregnant woman by allowing them to describe the symptom to have common understanding between pregnant women and the researcher. After they had realized their symptom and were aware of heartburn, they tended to provide the researcher with cooperation and follow the advice to deal with heartburn. If symptom experience was consistent with the occurring symptom, the symptom management program tended to be effective. If not, the symptom management program would not suitable (Dodd et al., 2001). After that, the research encouraged the samples to have self-care to deal with heartburn by equipping them with knowledge and appropriate and effective skills. In addition, the pregnant women were provided with the insights in suitable dietary and lifestyle modification since personal factors, health and illness and environmental factors affected heartburn experience and heartburn management strategies (Dodd et al., 2001). Moreover, there were continuous follow-up to support and encourage them to manage with heartburn together with the nurse who facilitated them to manage the symptom.

The frequency and the severity of heartburn in the experimental group were lower than the control group since the heartburn management program was a nursing activity to help reduce contributing factors leading to heartburn, for example, lifestyle and dietary modifications. The main causes of heartburn were the physiological changes during pregnancy which were not able to prevent. Following the study, it was reported that the main causes of heartburn were resulted from the changes in hormones and the expansion of uterus causing LES to relax (Lind et al., 1968; Monti, 2007; Nagler & Spiro, 1961; Richter, 2005; Van Thiel et al., 1977). However, those two factors did not lead every pregnant woman to encounter with heartburn because there were another predisposing factors causing heartburn, especially dietary behaviors and lifestyles (Audu & Mustapha, 2006; Bassey, 1977; Bor et al., 2007; Knudsen, Lebech, & Hansen, 1995; Naumann et al., 2012; Oliver et al., 2011). Therefore, the heartburn management strategies focused on reducing the contributing factors causing the symptom.

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Review of literature found that no study reported about heartburn management by means of lifestyle and dietary modifications in pregnant women. However, there was research by Lopes (2005) on the effectiveness of dietary management for pregnant women suffering from gastro-esophageal reflux disease. The research was a case study and there were 6 samples provided with knowledge about the symptom individually and giving booklet of lifestyle and dietary modifications. The samples were required to follow the instruction in the booklet for 30 days. It was found that the symptom occurring before and after the activity was not different with statistical significance. However, it was reported that the severity of symptom of four from the six samples came lower and the frequency of the symptom of two from the six samples was also lower. In addition, other studies also revealed that avoiding spicy food, citrus fruits and juices, acid food, fatty food, dessert, chocolate, tea, coffee and carbonated beverages was able to help reduce the frequency of heartburn since these types of food stimulated LES to relax, increased the higher chance of esophagus to expose to acid and irritated esophagus. Therefore, avoiding these types of food was good for pregnant women suffering from heartburn (Allen et al., 1990; Cranley et al., 1986; Dall'Alba et al., 2010; El-Serag et al., 2005; Fass et al., 2005; Feldman & Barnett, 1995; Hamoui et al., 2006; Iwakiri et al., 1996; Kaltenbach et al., 2006; Murphy & Castell, 1988; Nebel & Castell, 1973; Nebel et al., 1976; Oliver et al., 2011; Price et al., 1978; Salmon et al., 1981; Thomas et al., 1980; Wright & Castell, 1975). In addition, eating a small portion in each meal but increasing the number of meals in each day, avoiding late dinners, increasing the period time between meals, sleeping in a suitable position, elevating head of bed, sleeping in left lateral position, drinking suitable amount of water, avoiding alcohol and smoking and relaxing mind and body were good for pregnant women encountering with heartburn since they prevented too much gastric acid secretion which caused acids to reflux to esophagus and reduced factors leading LES to relax (Bhatia &Tandon, 2005; Bujanda, 2000; Dua et al., 1998; Grande et al., 1997; Hamilton et al., 1988; Jungsa-nga, 2012; Kadakia et al., 1995; Letsche, 2001; Lopes, 2005; Naliboff et al., 2004; Nilsson et al., 2004; Oliver et al., 2011; Ramu et al., 2011; Rubinstein et al., 1993; Schindlbeck et al., 1987; Stanciu& Bennett, 1977; Viriyautsahakul & Gonlachanvit, 2010; Wang et al., 2004). As a result, the frequency and the severity of heartburn in the experimental

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group provided with knowledge about suitable lifestyle and dietary modifications were lower with statistical significance at level .05. Also, it was found that the frequency and the severity of heartburn in the experimental group tended to reduce since the first week of the program and became apparently lower in the third and the fourth week of the program (Appendix L).

Moreover, it was found that the frequency and the severity of heartburn in the control group after finishing the program also were lower than before entering the program at significance level .05 since pregnant women in the control group had their own strategies to deal with heartburn. Half of the sample in the control group modified their diet and 70.8 percent adapted their behaviors and lifestyles. They did not report the symptom or ask for advice and treatment from the health care provider. However, upon considering the frequency and the severity of each sample in the control group, it was found that the frequency and the severity of heartburn of 20.83 percent and 58.33 percent in the control group were not lower, respectively. On the other hand, the frequency and the severity of heartburn of only 4.16 percent and 12.5 percent in the experimental group were not lower (Appendix L). Therefore, upon comparing between the control group and the experimental group, the frequency and the severity of heartburn in the experimental group were lower than the control group at significance level .05. The possible reasons were that since the main causes of heartburn were the changes in hormones and the expansion of uterus, occurring constantly during pregnancy, the pregnant women had a chance to suffer from heartburn all the time of the pregnancy. Although the symptom might disappear sometimes but if they ignored the symptom or did not continuously follow the advice and had suitable lifestyle and dietary modifications, the symptom tended to occur again. The experimental group participating in the heartburn management program was individually equipped with knowledge about suitable lifestyle and dietary modifications via the instruction tools containing pictures to help pregnant women understand symptom of heartburn. The instruction focused on two-way communication and discussion. Also, there was a concern on the issues of each pregnant woman to ensure that they were able to provide themselves with a self-care. Equipping pregnant women with the booklet of how to practice to reduce the severity and the frequency of heartburn to review at home was a strategy to encourage those in

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the experimental group to apply their knowledge in preventing prospective symptom. In addition, the nurses would follow up on the telephone once a week from the beginning to the end of the program to support and encourage pregnant women to manage with heartburn effectively and continually. As a result, the frequency and the severity of heartburn in the experimental group were clearly lower than the control group. This was consistent with the theory of Dodd et al. (2001) claiming that sufficient knowledge and skills could help enhance the potentials of an individual in self-care.

However, the findings of this research were not able to indicate the congruence with the findings of other studies since there was no research on the results of strategies to manage heartburn in pregnancy by lifestyle and dietary modifications.

The literature review found no research adopting the symptom management model of Dodd et al. to use in pregnant women suffering from heartburn. However, it was found that the symptom management model of Dodd et al. (2001) was utilized to develop symptom management programs for low back pain in pregnancy. Singkum (2005) conducted the study on the effect of the symptom management program on low back pain in pregnant women and the samples were pregnant women suffering from low back pain caused by bodily changes during pregnancy. The severity levels were from moderate to very severe, evaluated by visual analog scale (above 4 cm). There were total 40 pregnant women whose gestational age were between 30 and 32 weeks and were divided into an experimental group and a control group. The program covered five steps, including: 1) evaluating symptom experiences of low back pain in pregnant women, 2) giving advice to deal with low back pain, 3) enhancing skills in symptom management for low back pain in which pregnant women were required to follow the demonstration of the researchers, 4) practicing symptom management for low back pain at home, 5) assessing the outcomes of symptom management for low back pain in terms of symptom status after eight weeks of the program. The findings showed that the pregnant women who received the low back pain management program had significantly lower severity levels of low back pain than those who did not receive the program.

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In addition, the study carried out by Jannarong (2007) revealed that the low back pain management program could reduce pain levels and disability of

pregnant women. The samples were 60 pregnant women suffering from low back pain with the severity levels above level 2. Their gestational age was between 26 and 32 weeks and the samples were categorized into the experimental group and the control group. The program contained certain steps, including evaluating on the pain levels and disability before the program, equipping the samples with insight about symptoms, risk factors and causes of pain, offering the symptom management program to reduce pain, instructing appropriate movements in daily life and providing CD for exercising and return demonstration. In addition, the booklet for low back pain during pregnancy was distributed to pregnant women for reviewing and recording the practice at home. Moreover, followed up about the results by means of the 5-10 minute conversation on the telephone every week and had the evaluation of the program after four weeks. The findings disclosed that the pain scores and disability of the experimental group were lower than the control group. Following the findings of the research mentioned, adopting the symptom management model of Dodd et al. (2001), it was found that the program developed from the symptom management model was able to manage other unpleasant symptoms during pregnancy. Also, this study used the symptom management program and possessed the capacity to deal with the symptom was consistent with the above two studies and enhanced the symptom management model of Dodd et al. (2001).

Finally, it was concluded that the frequency and the severity of heartburn in the experimental group participating in the heartburn management program were lower than the control group who was equipped with only usual care. This showed that the heartburn management program developed from the symptom management model of Dodd et al. (2001) and the literature review related with heartburn in pregnancy was effective.

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CHAPTER VI
CONCLUSION

This quasi experimental research aimed to determine the effect of heartburn management program on frequency and severity of heartburn in pregnant women. The symptom management model developed by Dodd et al. (2001) was used as a conceptual framework of the study. The samples consisted of 48 pregnant women suffering from heartburn and attended prenatal clinic at Ramathibodi Hospital, Bangkok. The purposive samples were selected based on the inclusion criteria: 1) had normal pregnancy and were in 24-32 weeks of gestation, 2) experienced heartburn at least one time per week, 3) had never encountered with heartburn before pregnancy or had been diagnosed with gastro-esophageal reflux disease, esophagitis, peptic ulcer, and duodenal ulcer, 4) could verbal communicate, listen, read and write Thai language, and 5) were willing to participate in the study. The samples were divided into two groups, the experimental group and the control group, each group composed of 24 pregnant women. The experimental group received conventional health education program from nursing staff and heartburn management program from the researcher, whereas the control group received only conventional health education program from nursing staff. Data was collected from January to May 2015. The pregnant women suffering from heartburn who attended prenatal clinic on Monday were assigned into the control group, whereas those who received prenatal care on Wednesday and Friday were assigned into the experimental group.

There instruments used in this study included the instruments for implementing the study and the instruments for data collection. The instrument for implementing the study was the heartburn management program comprising of lesson plan for heartburn in pregnancy, instruction CD and booklet of “heartburn management during pregnancy. In addition, instruments for data collection included

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the demographic data questionnaire, the heartburn experience questionnaire, and the heartburn recording form.

The approval from the Committee on Human Right related to Researcher Involving Human Subjects at Faculty of Medicine Ramathibodi Hospital, Mahidol University was granted before carrying the study. Moreover, permission to conduct research was approved by the director of Ramathibodi Hospital, Bangkok. The eligible samples were approached and informed about purpose of the study, research procedures, and protection of human subjects. Those who were willing to participate in the study were asked to sign consent forms. In the first step of data collection, the samples in both groups were requested to fill out the demographic data questionnaire and the heartburn experience questionnaire. After that, the experimental group received conventional health education program combined with heartburn management program, whereas the control group received only conventional health education program. Evaluation of the program was done at the fourth week after the program was started.

The data was analyzed by a computer program and the confidence level .05 was set. Descriptive statistics; including frequency, percentages, mean and standard deviation was used to analyze the data regarding sample characteristics and heartburn experience. Moreover, chi-square test and independent t-test were used to compare sample characteristics of the experimental group and the control group. Wilcoxon signed ranks test and Mann-Whitney U Test were used to analyze the difference of the frequency and the severity of heartburn in the two groups sample.

Results of the study indicated that:

1. The frequency and the severity of heartburn in pregnant women in the experimental group after finishing the program was lower than before entering the program at the significance level .05 ($z = 4.22$, $p < .05$ and $z = 4.21$, $p < .05$ respectively).

2. The frequency and the severity of heartburn in pregnant women in the experimental group was lower than the control group at the significance level .05 ($z = -2.43$, $p < .05$ and $z = -2.83$, $p < .05$ respectively).

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Based on the finding of this study, heartburn management program was able to assist pregnant women experiencing heartburn reduce the frequency and the severity of the symptom.

Limitation

1. The subjects were selected by purposive sampling. Therefore, the study findings may not be generalized to other groups of pregnant women who have different demographic characteristics.

2. In this study, only the samples with gestation age between 24-32 weeks were included due to the limited time of the program; therefore, the pregnant women who were less than 24 weeks of gestation or more than 32 weeks of gestation may be missed.

Implications of the Study

Nursing Practice

1. Following the findings, it is suggested that the nurses in a prenatal clinic should be knowledgeable about causes, contributing factors, impacts of heartburn, and strategies to reduce heartburn. Assessment about the occurring of heartburn should be done in every pregnant woman during second-third trimester of pregnancy.

2. The heartburn management program should be regularly used in antenatal clinic in order to help the pregnant women alleviate heartburn during pregnancy.

3. The findings suggested that a copy of the booklet used in the heartburn management program should be distributed to pregnant women suffering from heartburn to promote self-care and self-symptom management. Individual counseling, continuous follow-up by phone call, and hotline service regarding heartburn in pregnancy should be set up.

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Nursing Education

The findings showed that the heartburn management program was effective to reduce the frequency and the severity of heartburn. Therefore, contents regarding heartburn in pregnancy and strategies used to reduce heartburn should be included the nursing curriculum.

Recommendations

Based on findings of this study, recommendation for further research are:

1. Effectiveness of heartburn management program should be explored in other settings and with the increase number of samples.

2. Gestational age of the sample in the study should be extended to 36 weeks of gestation.

3. The effect of heartburn management program on other outcomes such as quality of life or other impacts of heartburn should be investigated.

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APPENDICES

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APPENDIX A
LESSON PLANS FOR HEARTBURN IN PREGNANCY (THAI)

แผนการสอน

เรื่อง อาการแสบร้อนยอดอกในหญิงตั้งครรภ์

ผู้สอน นางสาวดรัลรัตน์ เชื้อเมืองแสน

ผู้เรียน หญิงตั้งครรภ์ช่วงอายุครรภ์ 24-32 สัปดาห์ที่มีอาการแสบร้อนยอดอก

สถานที่สอน คลินิกฝากครรภ์โรงพยาบาลรามาธิบดี

เวลาที่สอน 30 นาที

วัตถุประสงค์ทั่วไป

1. หญิงตั้งครรภ์ที่มีอาการแสบร้อนยอดอก มีความรู้เกี่ยวกับอาการแสบร้อนยอดอกในหญิงตั้งครรภ์
2. หญิงตั้งครรภ์ที่มีอาการแสบร้อนยอดอก สามารถนำความรู้ที่ได้ไปปฏิบัติในชีวิตประจำวันเพื่อลดอาการแสบร้อนยอดอกได้

เนื้อหาในการสอน ลักษณะอาการแสบร้อนยอดอก สาเหตุของการเกิดอาการ ปัจจัยส่งเสริมให้เกิดอาการ ผลกระทบของอาการต่อหญิงตั้งครรภ์ และหลักการปฏิบัติเพื่อลดอาการแสบร้อนยอดอกในขณะตั้งครรภ์

(Full version at the end of this book)

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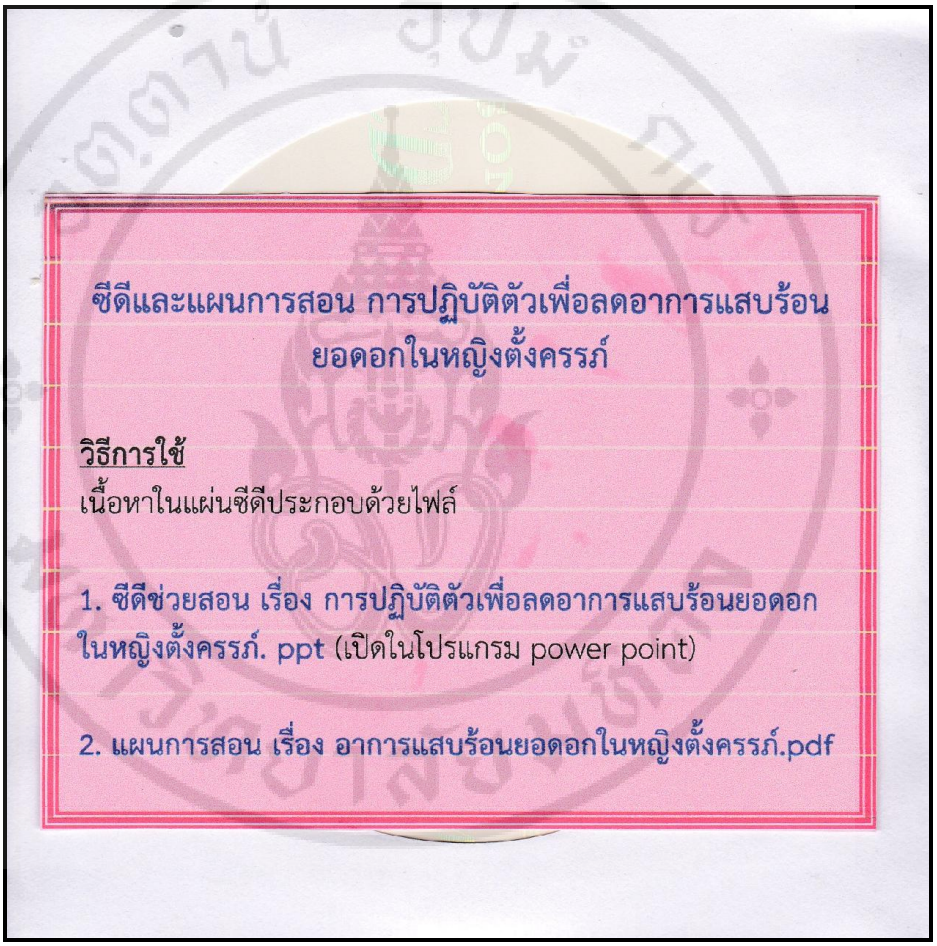
APPENDIX B

CD AND COMPUTER-BASED MEDIA (THAI)



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APPENDIX C
BOOKLET OF "HEARTBURN MANAGEMENT DURING PREGNANCY"

(Full version at the end of this book)

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APPENDIX D
DEMOGRAPHIC DATA QUESTIONNAIRE (THAI)

ลำดับที่.....

วันที่.....

คำชี้แจง กรุณาทำเครื่องหมาย√ ลงใน □ (ช่องสี่เหลี่ยม) หรือเติมข้อมูลให้ครบถ้วนตามความเป็นจริง

1. อายุ.....ปี

2. อาชีพ

□ …… □ ……..

□ …… □ ……

□ อื่นๆ.....

3. ระดับการศึกษา

□ …….. □ …….

4. รายได้ครอบครัวต่อเดือน .....บาท

5. ตั้งครรภ์ครั้งที่.....

6. อายุครรภ์ .....สัปดาห์

7. น้ำหนักก่อนการตั้งครรภ์.....กิโลกรัม ส่วนสูง.....เซนติเมตร

น้ำหนักปัจจุบัน.....กิโลกรัม

8. เบอร์โทรศัพท์ที่สามารถติดต่อได้.....

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APPENDIX E
HEARTBURN EXPERIENCE QUESTIONNAIRE (THAI)

ลำดับที่.....

วันที่.....

คำชี้แจง กรุณาทำเครื่องหมาย√ ลงใน □ (ช่องสี่เหลี่ยม) หรือเติมข้อมูลให้ครบถ้วนตามความเป็นจริง

1) ท่านเริ่มมีอาการแสบร้อนยอดอกเมื่ออายุครรภ์.....เดือน

2) อาการใดตรงกับลักษณะอาการที่เกิดขึ้นกับท่าน (ตอบได้มากกว่า 1 คำตอบ)

□ ปวดแสบร้อนเหมือนมีไฟเผาบริเวณกลางอก

□ ……..

3) อาการแสบร้อนยอดอกมักเกิดในช่วงเวลาใด

□ กลางวัน

□ ……..

4) …….

5) ……

6) อาการแสบร้อนยอดอกที่เกิดขึ้นกับท่านรุนแรงมากเพียงใด

□ ……..

7) ท่านคิดอย่างไรกับอาการแสบร้อนยอดอกของท่าน (ตอบได้มากกว่า 1 คำตอบ)

□ …….

□ …….

8) ท่านจัดการกับอาการแสบร้อนยอดอกที่เกิดขึ้นอย่างไร (ตอบได้มากกว่า 1 คำตอบ)

□ …….

□ …….

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APPENDIX F
HEARTBURN RECORDING FORM (THAI)

ลำดับที่.....

วันที่.....

1. แบบบันทึกความถี่ของการเกิดอาการแสบร้อนยอดอก

<u>คำชี้แจงในการตอบคำถาม</u>

แบบสอบถามชุดนี้ มีวัตถุประสงค์เพื่อต้องการทราบว่าอาการแสบร้อนยอดอกที่เกิดขึ้นกับท่าน มีความถี่มากน้อยเพียงใดในแต่ละสัปดาห์ โดยกรุณาตอบจำนวนวันที่เกิดอาการในแต่ละสัปดาห์

จำนวนวันที่มีอาการ			
สัปดาห์ที่ 1	**สัปดาห์ที่ 2**	**สัปดาห์ที่ 3**	**สัปดาห์ที่ 4**

หมายเหตุ: กรณีที่สัปดาห์ใดไม่มีอาการ ท่านไม่ต้องบันทึกระดับความรุนแรงของอาการในสัปดาห์นั้น

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ลำดับที่.....

วันที่.....

2. **แบบบันทึกระดับความรุนแรงของอาการแสบร้อนยอดอก**

<u>คำชี้แจงในการตอบคำถาม</u>

แบบสอบถามชุดนี้ มีวัตถุประสงค์เพื่อต้องการทราบว่าอาการแสบร้อนยอดอกที่เกิดขึ้นกับท่านมีความรุนแรงมากน้อยเพียงใดในระยะเวลา 4 สัปดาห์ กรุณาทำเครื่องหมาย√ ลงในช่องว่างที่ตรงกับการรับรู้ของท่านต่ออาการแสบร้อนยอดอกที่เกิดขึ้น โดยใช้เกณฑ์ในการเลือกตอบดังนี้

ระดับเล็กน้อย หมายถึง .....

ระดับปานกลาง หมายถึง .....

ระดับรุนแรง หมายถึง .....

สัปดาห์	**ความรุนแรงของอาการแสบร้อนยอดอก**		
	เล็กน้อย	**ปานกลาง**	**รุนแรง**
สัปดาห์ที่ 1			
สัปดาห์ที่ 2			
สัปดาห์ที่ 3			
สัปดาห์ที่ 4			

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APPENDIX G
LIST OF EXPERTS

List of experts consulted on validation of the instrument

1. Assistant Professor Pranom Poosrithong
   Department of Maternal-Newborn Nursing and Midwifery,
   School of Nursing,Faculty of Medicine Ramathibodi Hospital, Mahidol University

2. Lecturer Pranee Pongrua
   Department of Maternal-Newborn Nursing and Midwifery,
   School of Nursing,Faculty of Medicine Ramathibodi Hospital, Mahidol University

3. Mrs. NathataiVannatim (Registered Nurse)
   Acting Head Nurse of Prenatal Clinic of Ramathibodi Hospital

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APPENDIX H
INFORMED CONSENT FORM (THAI)

หนังสือยินยอมโดยได้รับการบอกกล่าวและเต็มใจ

การวิจัยเรื่อง "ผลของโปรแกรมการจัดการอาการแสบร้อนยอดอกต่อความถี่และความรุนแรงของอาการแสบร้อนยอดอกในหญิงตั้งครรภ์"

ชื่อผู้วิจัย นางสาวดรัลรัตน์ เชื้อเมืองแสน

*ชื่อผู้เข้าร่วมการวิจัย .....

อายุ ..... เลขที่เวชระเบียน .....

คำยินยอมของผู้เข้าร่วมการวิจัย

ข้าพเจ้า นาง/นางสาว ..... ได้ทราบรายละเอียดของโครงการวิจัยตลอดจนประโยชน์ และข้อเสี่ยงที่จะเกิดขึ้นต่อข้าพเจ้าจากผู้วิจัยแล้วอย่างชัดเจน ไม่มีสิ่งใดปิดบังซ่อนเร้นและยินยอมให้ทำการวิจัยในโครงการที่มีชื่อข้างต้น และข้าพเจ้ารู้ว่าถ้ามีปัญหาหรือข้อสงสัยเกิดขึ้น ข้าพเจ้าสามารถสอบถามผู้วิจัยได้ และข้าพเจ้าสามารถไม่เข้าร่วมโครงการวิจัยนี้เมื่อใดก็ได้ โดยไม่มีผลกระทบต่อการรักษาที่ข้าพเจ้าพึงได้รับ นอกจากนี้ผู้วิจัยจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวข้าพเจ้าเป็นความลับและจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย การเปิดเผยข้อมูลเกี่ยวกับตัวข้าพเจ้าต่อหน่วยงานต่างๆที่เกี่ยวข้อง กระทำได้เฉพาะกรณีจำเป็นด้วยเหตุผลทางวิชาการเท่านั้น

ลงชื่อ.....(ผู้เข้าร่วมการวิจัย)

.....(พยาน)

.....(พยาน)

วันที่ .....

คำอธิบายของแพทย์หรือผู้วิจัย

ข้าพเจ้าได้อธิบายรายละเอียดของโครงการ ตลอดจนประโยชน์ของการวิจัย รวมทั้งข้อเสี่ยงที่อาจจะเกิดขึ้นแก่ผู้เข้าร่วมการวิจัยทราบแล้วอย่างชัดเจนโดยไม่มีสิ่งใดปิดบังซ่อนเร้น

ลงชื่อ.....(แพทย์หรือผู้วิจัย)

วันที่.....

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หมายเหตุ : กรณีผู้เข้าร่วมการวิจัยไม่สามารถอ่านหนังสือได้ ให้ผู้วิจัยอ่านข้อความในหนังสือยินยอมฯ นี้ให้แก่ผู้เข้าร่วมการวิจัยฟังจนเข้าใจดีแล้ว และให้ผู้เข้าร่วมการวิจัยลงนามหรือพิมพ์ลายนิ้วหัวแม่มือรับทราบในการให้ความยินยอมดังกล่าวข้างต้นไว้ด้วย * ผู้เข้าร่วมการวิจัย หมายถึง ผู้ยินยอมตนให้ทำวิจัย

APPENDIX I
PARTICIPANT INFORMATION SHEET (THAI)

เอกสารชี้แจงข้อมูล/คำแนะนำแก่ผู้เข้าร่วมการวิจัย สำหรับกลุ่มควบคุม

(Patient/Participant Information Sheet for control group)

หัวข้อเรื่องการวิจัย "ผลของโปรแกรมการจัดการอาการแสบร้อนยอดอก ต่อความถี่และความรุนแรงของอาการแสบร้อนยอดอกในหญิงตั้งครรภ์"

ผู้วิจัย นางสาวดรัลรัตน์ เชื้อเมืองแสน

สถานที่วิจัย คลินิกฝากครรภ์ แผนกผู้ป่วยนอกสูติ-นรีเวชกรรม โรงพยาบาลรามาธิบดี

บุคคลและวิธีการติดต่อเมื่อมีเหตุฉุกเฉินหรือความผิดปกติที่เกี่ยวข้องกับการวิจัย

1. นางสาวดรัลรัตน์ เชื้อเมืองแสน หมายเลขโทรศัพท์ 086-221-5208

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2. ผศ.ดร. จันทิมา ขนบดี หมายเลขโทรศัพท์ 085-158-7630

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ความเป็นมาของโครงการ

ระยะตั้งครรภ์เป็นช่วงที่ร่างกายมีการเปลี่ยนแปลงเพื่อปรับให้เกิดสภาพที่เหมาะสม พร้อมรับการเจริญเติบโตของทารกในครรภ์ และประคับประคองการตั้งครรภ์ให้ดำเนินไปจนสิ้นสุดกระบวนการตั้งครรภ์ ซึ่งการเปลี่ยนแปลงนี้จะเกิดขึ้นต่อเนื่องตลอดการตั้งครรภ์ การเปลี่ยนแปลงของร่างกายในขณะตั้งครรภ์ดังกล่าวนี้ อาจก่อให้เกิดความไม่สุขสบายแก่หญิงตั้งครรภ์ ดังเช่น อาการแสบร้อนยอดอก ซึ่งเป็นอาการไม่สุขสบายที่พบได้บ่อยในไตรมาสที่สองและสามของการตั้งครรภ์ มีสาเหตุหลักมาจากการเพิ่มขึ้นของฮอร์โมนและการขยายใหญ่ของมดลูก และปัจจัยกระตุ้นอื่นๆ โดยเฉพาะอาหารและพฤติกรรมที่ไม่เหมาะสมบางประการ อาการที่เกิดขึ้นอาจส่งผลให้หญิงตั้งครรภ์เกิดความไม่สุขสบาย รบกวนแบบแผนการรับประทานอาหารและการนอนหลับ แม้อาการที่เกิดขึ้นจะไม่ก่อให้เกิดอันตราย แต่หากละเลยไม่ได้รับการดูแลอย่างเหมาะสมอาจ

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ก่อให้เกิดภาวะแทรกซ้อนเช่นโรคกรดไหลย้อน หลอดอาหารอักเสบตามมาได้ จากการทบทวนวรรณกรรมพบว่าหญิงตั้งครรภ์ที่มีอาการแสบร้อนยอดอกมีการรับรู้ต่ออาการว่าเป็นภาวะปกติที่เกิดขึ้นได้ในช่วงตั้งครรภ์ เมื่อเกิดอาการจึงไม่มีการจัดการอาการ หรือหญิงตั้งครรภ์บางกลุ่มเลือกจัดการกับอาการด้วยวิธีของตนเองซึ่งพบว่าบางวิธีที่เลือกใช้ไม่เหมาะสม เช่นการใช้ยา หรือสมุนไพร ซึ่งปัญหาดังกล่าวเกิดจากการรับรู้ต่ออาการที่เกิดขึ้นไม่เหมาะสม รวมไปถึงความรู้เกี่ยวกับกลวิธีในการจัดการอาการแสบร้อนยอดอกยังไม่เพียงพอ ซึ่งการรับรู้อาการที่เหมาะสมและสอดคล้องกันระหว่างพยาบาลและหญิงตั้งครรภ์จะส่งผลให้หญิงตั้งครรภ์ปฏิบัติตามกลวิธีการจัดการกับอาการที่เหมาะสม และหากหญิงตั้งครรภ์ได้รับความรู้ ทักษะ การกระตุ้นและสนับสนุนจากพยาบาลอย่างเพียงพอจะช่วยเพิ่มศักยภาพให้หญิงตั้งครรภ์สามารถจัดการกับอาการแสบร้อนยอดอกด้วยตนเองอย่างมีประสิทธิภาพ ผู้วิจัยจึงเห็นว่าควรมีการปรับการรับรู้และให้ความรู้เกี่ยวกับการจัดการอาการแสบร้อนอดอก เพื่อให้หญิงตั้งครรภ์มีการจัดการอาการแสบร้อนยอดอกด้วยตนเองที่เหมาะสม คงไว้ซึ่งความสุขสบายและภาวะสุขภาพที่ดีในระยะตั้งครรภ์

ดังนั้นผู้วิจัยจึงมีความสนใจในการจัดกิจกรรมปรับประสบการณ์การมีอาการและให้ความรู้เกี่ยวกับการจัดการอาการแสบร้อนยอดอกโดยการปรับเปลี่ยนวิถีชีวิตและการรับประทานอาหารเพื่อลดปัจจัยกระตุ้นให้เกิดอาการแสบร้อนยอดอกในหญิงตั้งครรภ์ โดยมุ่งหวังว่าหญิงตั้งครรภ์ที่มีอาการแสบร้อนยอดอกจะมีความถี่และความรุนแรงของอาการแสบร้อนยอดอกลดลง สามารถดำเนินการตั้งครรภ์ได้อย่างมีคุณภาพทั้งด้านร่างกายและจิตใจ มีคุณภาพชีวิตที่ดี รวมถึงเป็นแนวทางในการพัฒนาคุณภาพการพยาบาลต่อไป

วัตถุประสงค์

1. เพื่อเปรียบเทียบความถี่ และความรุนแรงของการเกิดอาการแสบร้อนยอดอกของหญิงตั้งครรภ์ก่อนและหลังได้รับโปรแกรมการจัดการอาการแสบร้อนยอดอก

2. เพื่อเปรียบเทียบความถี่ และความรุนแรงของการเกิดอาการแสบร้อนยอดอกของหญิงตั้งครรภ์ระหว่างกลุ่มที่ได้รับโปรแกรมการจัดการอาการแสบร้อนยอดอกกับกลุ่มที่ได้รับการพยาบาลตามปกติ

รายละเอียดที่จะปฏิบัติต่อผู้เข้าร่วมการวิจัย

การศึกษาวิจัยครั้งนี้เป็นการวิจัยกึ่งทดลอง แบบสองกลุ่มวัดก่อนและหลังการทดลองในหญิงตั้งครรภ์ปกติ อายุครรภ์ 24-32 สัปดาห์ มีอาการแสบร้อนยอดอกในระยะตั้งครรภ์ ผู้วิจัยคัดเลือกกลุ่มตัวอย่างหญิงตั้งครรภ์ที่มีคุณสมบัติตามเกณฑ์ที่กำหนด โดยแบ่งกลุ่มตัวอย่างออกเป็น

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กลุ่มควบคุม 24 ราย และกลุ่มทดลอง 24 ราย รวมกลุ่มตัวอย่างทั้งหมด 48 ราย การจัดให้เกิดความสมดุลกันระหว่างกลุ่มทดลองและกลุ่มควบคุมในด้านจำนวนครั้งที่ตั้งครรภ์ อายุครรภ์ อายุหญิงตั้งครรภ์ ดัชนีมวลกายก่อนตั้งครรภ์ ความถี่และความรุนแรงของอาการ เก็บรวบรวมข้อมูลหญิงตั้งครรภ์ที่มีอาการแสบร้อนยอดอกที่มารับบริการฝากครรภ์ในทุกๆวันจันทร์จัดเข้าเป็นกลุ่มควบคุม 24 ราย และหญิงตั้งครรภ์ที่มีอาการแสบร้อนยอดอกที่มารับบริการฝากครรภ์ในทุกๆวันพุธและวันศุกร์จัดเข้าเป็นกลุ่มทดลอง 24 ราย ใช้ระยะเวลาในการดำเนินการ 4 สัปดาห์ โดยมีการดำเนินการทดลองสำหรับกลุ่มควบคุมตามขั้นตอนต่อไปนี้

1. ผู้วิจัยศึกษาแฟ้มประวัติของท่าน จากนั้นผู้วิจัยเข้าแนะนำตัว สร้างสัมพันธภาพเพื่อสอบถามข้อมูลการมีอาการแสบร้อนยอดอกจากท่านโดยตรง และคัดเลือกท่านเข้ากลุ่มควบคุมตามเกณฑ์ที่กำหนดไว้

2. ผู้วิจัยแนะนำตัว สร้างสัมพันธภาพ แจ้งวัตถุประสงค์และวิธีการ ขั้นตอนในการดำเนินวิจัยอย่างละเอียด อธิบายถึงการพิทักษ์สิทธิผู้เข้าร่วมวิจัยและขอความร่วมมือในการเข้าร่วมการวิจัย หากท่านสนใจและยินดีเข้าร่วมการวิจัย ให้ท่านลงลายมือชื่อไว้เป็นลายลักษณ์อักษรในหนังสือยินยอมให้ทำการวิจัยโดยได้รับการบอกกล่าวและเต็มใจ

3. ผู้วิจัยขอให้ท่านตอบแบบสอบถามทั้งหมด 2 ชุด ได้แก่ แบบสอบถามข้อมูลส่วนบุคคล และ แบบสอบถามประสบการณ์การมีอาการและการจัดการอาการแสบร้อนยอดอก โดยใช้เวลาในการตอบ 5-10 นาที ขณะตอบแบบสอบถามผู้วิจัยจะอยู่ในบริเวณใกล้เคียงที่ท่านสามารถซักถามข้อสงสัยได้ตลอดเวลา

4. หลังจากนั้นให้ท่านได้รับการพยาบาลตามปกติจากสูติแพทย์หรือพยาบาลวิชาชีพ

5. ผู้วิจัยนัดพบท่านในสัปดาห์ที่ 4 ที่ตรงกับการนัดตรวจครรภ์ตามปกติของท่าน เพื่อขอให้ท่านตอบคำถามเกี่ยวกับความถี่และความรุนแรงของอาการแสบร้อนยอดอกของท่านในสัปดาห์นั้น ใช้เวลา 5 – 10 นาที ซึ่งถือว่าสิ้นสุดการเข้าร่วมโครงการวิจัย

ประโยชน์และผลข้างเคียงที่จะเกิดแก่ผู้เข้าร่วมการวิจัย:

ประโยชน์ที่คาดว่าจะเกิดขึ้นต่อผู้เข้าร่วมการวิจัย และต่อผู้อื่น

การศึกษาครั้งนี้ เป็นการศึกษาขณะที่ท่านมาตรวจครรภ์ในคลินิกฝากครรภ์ ซึ่งท่านจะยังคงได้รับการดูแลจากแพทย์ พยาบาลและเจ้าหน้าที่ทางการพยาบาลของคลินิกฝากครรภ์ตามปกติ และผลที่ได้จากการศึกษาครั้งนี้จะเป็นประโยชน์คือ เป็นแนวทางแก่บุคลากรทีมสุขภาพในการดูแลหญิงตั้งครรภ์ที่มีอาการแสบร้อนยอดอกต่อไปในอนาคต

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ผลข้างเคียงที่อาจเกิดขึ้นกับผู้เข้าร่วมการวิจัย

ไม่มีความเสี่ยงใดๆ ที่จะเกิดขึ้นกับท่าน แต่ในการตอบแบบสอบถามอาจทำให้ท่านต้องใช้เวลาในการอ่านและตอบแบบสอบถาม ซึ่งในการเข้าร่วมวิจัยครั้งนี้จะเป็นไปตามความสมัครใจ การตอบรับหรือปฏิเสธเข้าร่วมวิจัยจะไม่มีผลกระทบใดๆต่อการรับบริการ การรักษาพยาบาลหรือการสูญเสียประโยชน์ใดๆที่ท่านพึงจะได้รับ

การเก็บข้อมูลเป็นความลับ

ผู้วิจัยจะเก็บข้อมูลของท่าน ไว้เป็นความลับ จะเปิดเผยได้เฉพาะในรูปที่เป็นผลสรุปการวิจัยในภาพรวม การเปิดเผยข้อมูลต่อหน่วยงานต่างๆที่เกี่ยวข้องกระทำได้ในเฉพาะกรณีจำเป็นด้วยเหตุผลทางวิชาการเท่านั้น และในการวิจัยครั้งนี้ ผู้วิจัยจะไม่ระบุชื่อผู้ร่วมวิจัยลงในแบบบันทึกต่างๆ โดยจะใช้รหัสแทนผู้เข้าร่วมวิจัยแต่ละราย และผู้ที่จะสามารถรับรู้ข้อมูลเหล่านี้นอกจากผู้วิจัยและอาจารย์ที่ปรึกษาแล้วต้องได้รับความยินยอมจากท่านก่อน

ถ้าท่านมีปัญหาข้องใจหรือรู้สึกกังวลใจกับการเข้าร่วมในโครงการวิจัยนี้ ท่านสามารถติดต่อกับประธานกรรมการจริยธรรมการวิจัยในคน สำนักงานวิจัยคณะฯ อาคารวิจัยและสวัสดิการ คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี โทรศัพท์ 02-2011544

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เอกสารชี้แจงข้อมูล/คำแนะนำแก่ผู้เข้าร่วมการวิจัย สำหรับกลุ่มทดลอง

(Patient/Participant Information Sheet for experimental group)

หัวข้อเรื่องการวิจัย "ผลของโปรแกรมการจัดการอาการแสบร้อนยอดอก ต่อความถี่และความรุนแรงของอาการแสบร้อนยอดอกในหญิงตั้งครรภ์"

ผู้วิจัย นางสาวดรัลรัตน์ เชื้อเมืองแสน

สถานที่วิจัย คลินิกฝากครรภ์ แผนกผู้ป่วยนอกสูติ-นรีเวชกรรม โรงพยาบาลรามาธิบดี

บุคคลและวิธีการติดต่อเมื่อมีเหตุฉุกเฉินหรือความผิดปกติที่เกี่ยวข้องกับการวิจัย

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ความเป็นมาของโครงการ

ระยะตั้งครรภ์เป็นช่วงที่ร่างกายมีการเปลี่ยนแปลงเพื่อปรับให้เกิดสภาพที่เหมาะสม พร้อมรับการเจริญเติบโตของทารกในครรภ์ และประคับประคองการตั้งครรภ์ให้ดำเนินไปจนสิ้นสุดกระบวนการตั้งครรภ์ ซึ่งการเปลี่ยนแปลงนี้จะเกิดขึ้นต่อเนื่องตลอดการตั้งครรภ์ การเปลี่ยนแปลงของร่างกายในขณะตั้งครรภ์ดังกล่าวนี้ อาจก่อให้เกิดความไม่สุขสบายแก่หญิงตั้งครรภ์ ดังเช่น อาการแสบร้อนยอดอก ซึ่งเป็นอาการไม่สุขสบายที่พบได้บ่อยในไตรมาสที่สองและสามของการตั้งครรภ์ มีสาเหตุหลักมาจากการเพิ่มขึ้นของฮอร์โมนและการขยายใหญ่ของมดลูก และปัจจัยกระตุ้นอื่นๆ โดยเฉพาะอาหารและพฤติกรรมที่ไม่เหมาะสมบางประการ อาการที่เกิดขึ้นอาจส่งผลให้หญิงตั้งครรภ์เกิดความไม่สุขสบาย รบกวนแบบแผนการรับประทานอาหารและการนอนหลับ แม้อาการที่เกิดขึ้นจะไม่ก่อให้เกิดอันตราย แต่หากละเลยไม่ได้รับการดูแลอย่างเหมาะสมอาจก่อให้เกิดภาวะแทรกซ้อนเช่นโรคกรดไหลย้อน หลอดอาหารอักเสบตามมาได้ จากการทบทวนวรรณกรรมพบว่าหญิงตั้งครรภ์ที่มีอาการแสบร้อนยอดอกมีการรับรู้ต่ออาการว่าเป็นภาวะปกติที่เกิดขึ้นได้ในช่วงตั้งครรภ์ เมื่อเกิดอาการจึงไม่มีการจัดการอาการ หรือหญิงตั้งครรภ์บางกลุ่มเลือกจัดการกับอาการด้วยวิธีของตนเองซึ่งพบว่าบางวิธีที่เลือกใช้ไม่เหมาะสม เช่นการใช้ยา หรือ

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สมุนไพร ซึ่งปัญหาดังกล่าวเกิดจากการรับรู้ต่ออาการที่เกิดขึ้นไม่เหมาะสม รวมไปถึงความรู้เกี่ยวกับกลวิธีในการจัดการอาการแสบร้อนยอดอกยังไม่เพียงพอ ซึ่งการรับรู้อาการที่เหมาะสมและสอดคล้องกันระหว่างพยาบาลและหญิงตั้งครรภ์จะส่งผลให้หญิงตั้งครรภ์ปฏิบัติตามกลวิธีการจัดการกับอาการที่เหมาะสม และหากหญิงตั้งครรภ์ได้รับความรู้ ทักษะ การกระตุ้นและสนับสนุนจากพยาบาลอย่างเพียงพอจะช่วยเพิ่มศักยภาพให้หญิงตั้งครรภ์สามารถจัดการกับอาการแสบร้อนยอดอกด้วยตนเองอย่างมีประสิทธิภาพ ผู้วิจัยจึงเห็นว่าควรมีการปรับการรับรู้และให้ความรู้เกี่ยวกับการจัดการอาการแสบร้อนอดอก เพื่อให้หญิงตั้งครรภ์มีการจัดการอาการแสบร้อนยอดอกด้วยตนเองที่เหมาะสม คงไว้ซึ่งความสุขสบายและภาวะสุขภาพที่ดีในระยะตั้งครรภ์

ดังนั้นผู้วิจัยจึงมีความสนใจในการจัดกิจกรรมปรับประสบการณ์การมีอาการและให้ความรู้เกี่ยวกับการจัดการอาการแสบร้อนยอดอกโดยการปรับเปลี่ยนวิถีชีวิตและการรับประทานอาหารเพื่อลดปัจจัยกระตุ้นให้เกิดอาการแสบร้อนยอดอกในหญิงตั้งครรภ์ โดยมุ่งหวังว่าหญิงตั้งครรภ์ที่มีอาการแสบร้อนยอดอกจะมีความถี่และความรุนแรงของอาการแสบร้อนยอดอกลดลง สามารถดำเนินการตั้งครรภ์ได้อย่างมีคุณภาพทั้งด้านร่างกายและจิตใจ มีคุณภาพชีวิตที่ดี รวมถึงเป็นแนวทางในการพัฒนาคุณภาพการพยาบาลต่อไป

วัตถุประสงค์

1. เพื่อเปรียบเทียบความถี่ และความรุนแรงของการเกิดอาการแสบร้อนยอดอกของหญิงตั้งครรภ์ก่อนและหลังได้รับโปรแกรมการจัดการอาการแสบร้อนยอดอก

2. เพื่อเปรียบเทียบความถี่ และความรุนแรงของการเกิดอาการแสบร้อนยอดอกของหญิงตั้งครรภ์ระหว่างกลุ่มที่ได้รับโปรแกรมการจัดการอาการแสบร้อนยอดอกกับกลุ่มที่ได้รับการพยาบาลตามปกติ

รายละเอียดที่จะปฏิบัติต่อผู้เข้าร่วมการวิจัย

การศึกษาวิจัยครั้งนี้เป็นการวิจัยกึ่งทดลอง แบบสองกลุ่มวัดก่อนและหลังการทดลอง ในหญิงตั้งครรภ์ปกติ อายุครรภ์ 24-32 สัปดาห์ มีอาการแสบร้อนยอดอกในระยะตั้งครรภ์ ผู้วิจัยคัดเลือกกลุ่มตัวอย่างหญิงตั้งครรภ์ที่มีคุณสมบัติตามเกณฑ์ที่กำหนด โดยแบ่งกลุ่มตัวอย่างออกเป็นกลุ่มควบคุม 24 ราย และกลุ่มทดลอง 24 ราย รวมกลุ่มตัวอย่างทั้งหมด 48 ราย การจัดให้เกิดความสมดุลกันระหว่างกลุ่มทดลองและกลุ่มควบคุมในด้านจำนวนครั้งที่ตั้งครรภ์ อายุครรภ์ อายุหญิงตั้งครรภ์ ดัชนีมวลกายก่อนตั้งครรภ์ ความถี่และความรุนแรงของอาการ เก็บรวบรวมข้อมูลหญิงตั้งครรภ์ที่มีอาการแสบร้อนยอดอกที่มารับบริการฝากครรภ์ในทุกๆวันจันทร์จัดเข้าเป็นกลุ่มควบคุม

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24 ราย และหญิงตั้งครรภ์ที่มีอาการแสบร้อนยอดอกที่มารับบริการฝากครรภ์ในทุกๆวันพุธและวันศุกร์จัดเข้าเป็นกลุ่มทดลอง 24 ราย ใช้ระยะเวลาในการดำเนินการ 4 สัปดาห์ โดยมีการดำเนินการทดลองสำหรับกลุ่มทดลองตามขั้นตอนต่อไปนี้

1. ผู้วิจัยศึกษาแฟ้มประวัติของท่าน จากนั้นผู้วิจัยเข้าแนะนำตัว สร้างสัมพันธภาพเพื่อสอบถามข้อมูลการมีอาการแสบร้อนยอดอกจากท่านโดยตรง และคัดเลือกท่านเข้ากลุ่มทดลองตามเกณฑ์ที่กำหนดไว้

2. ผู้วิจัยแนะนำตัว สร้างสัมพันธภาพ แจ้งวัตถุประสงค์และวิธีการ ขั้นตอนในการดำเนินวิจัยอย่างละเอียด อธิบายถึงการพิทักษ์สิทธิผู้เข้าร่วมวิจัยและขอความร่วมมือในการเข้าร่วมการวิจัย หากท่านสนใจและยินดีเข้าร่วมการวิจัย ให้ท่านลงลายมือชื่อไว้เป็นลายลักษณ์อักษรในหนังสือยินยอมให้ทำการวิจัยโดยได้รับการบอกกล่าวและเต็มใจ

3. ผู้วิจัยให้ท่านตอบแบบสอบถามทั้งหมด 2 ชุด ได้แก่ แบบสอบถามข้อมูลส่วนบุคคล และ แบบสอบถามประสบการณ์การมีอาการและการจัดการอาการแสบร้อนยอดอก โดยใช้เวลาในการตอบ 5-10 นาที ขณะตอบแบบสอบถามผู้วิจัยจะอยู่ในบริเวณใกล้เคียงที่ท่านสามารถซักถามข้อสงสัยได้ตลอดเวลา

4. หลังจากนั้นให้ท่านได้รับการพยาบาลตามปกติจากสูติแพทย์หรือพยาบาลวิชาชีพ

5. ผู้วิจัยให้การดูแลท่านตามโปรแกรมการจัดการอาการแสบร้อนยอดอก โดย

5.1 ให้ความรู้รายบุคคล เกี่ยวกับสาเหตุของการเกิดอาการแสบร้อนยอดอก ปัจจัยเสี่ยงที่กระตุ้นให้เกิดอาการ ผลกระทบของอาการแสบร้อนยอดอกที่เกิดขึ้น ประโยชน์และความสำคัญในการปรับเปลี่ยนวิถีชีวิตและการรับประทานอาหาร วิธีการปรับเปลี่ยนพฤติกรรมวิถีชีวิตและการรับประทานอาหารที่เหมาะสมในหญิงตั้งครรภ์ที่มีอาการแสบร้อนยอดอก ระยะเวลาในการให้ความรู้ประมาณ 30 นาที ที่ห้องให้ความรู้ของคลินิกฝากครรภ์ ซึ่งเป็นห้องที่มีความเป็นส่วนตัว แยกจากกิจกรรมอื่นๆในคลินิก

5.2 ผู้วิจัยแจกสมุดคู่มือการปฏิบัติตัวเพื่อลดอาการแสบร้อนยอดอกสำหรับทบทวนที่บ้าน

5.3 ผู้วิจัยอธิบายการลงบันทึกในแบบบันทึกอาการแสบร้อนยอดอก

5.4 หลังจากนั้นนัดหมายท่านและขออนุญาตติดตามทางโทรศัพท์ ในสัปดาห์ที่ 1-3 โทรศัพท์ตามช่วงเวลาที่ท่านสะดวกสัปดาห์ละหนึ่งครั้ง ครั้งละ 5-10 นาที เพื่อกระตุ้นส่งเสริมและสนับสนุนให้นำความรู้ที่ได้รับตามโปรแกรมไปปฏิบัติอย่างต่อเนื่อง

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5.5 ผู้วิจัยนัดพบท่านในสัปดาห์ที่ 4 ที่ตรงกับการนัดตรวจครรภ์ตามปกติของท่านเพื่อรวบรวมผลการบันทึกความถี่และความรุนแรงของอาการแสบร้อนยอดอกในแบบบันทึกอาการแสบร้อนยอดอกที่ท่านทำการบันทึกไว้ ใช้เวลา 5 – 10 นาที

5.6 ผู้วิจัยสรุปผลการดำเนินตามโปรแกรมและกล่าวขอบคุณท่านที่ให้ความร่วมมือ ซึ่งถือว่าสิ้นสุดการเข้าร่วมโครงการวิจัย

ประโยชน์และผลข้างเคียงที่จะเกิดแก่ผู้เข้าร่วมการวิจัย:

ประโยชน์ที่คาดว่าจะเกิดขึ้นต่อผู้เข้าร่วมการวิจัย และต่อผู้อื่น

หญิงตั้งครรภ์ที่มีอาการแสบร้อนยอดอกที่เข้าร่วมการวิจัย มีความรู้ ความเข้าใจถึงสาเหตุปัจจัยส่งเสริมให้เกิดอาการแสบร้อนยอดอกและสามารถจัดการอาการแสบร้อนยอดอกได้ด้วยตนเอง โดยการปรับพฤติกรรม วิถีชีวิตและการรับประทานอาหารให้เหมาะสม เพื่อลดความถี่และความรุนแรงของอาการที่เกิดขึ้น และผลที่ได้จากการศึกษาจะเป็นแนวทางในการดูแลหญิงตั้งครรภ์ที่มีอาการแสบร้อนยอดอกต่อไปในอนาคต

ผลข้างเคียงที่อาจเกิดขึ้นกับผู้เข้าร่วมการวิจัย

เนื่องจากในการวิจัยครั้งนี้ ท่านจะได้รับการดูแลตามมาตรฐานจากบุคลากรทางการแพทย์และการพยาบาลร่วมกับผู้วิจัย และโปรแกรมการจัดการอาการแสบร้อนยอดอกได้รับการตรวจสอบความถูกต้องและเหมาสมในการนำไปปฏิบัติกับหญิงตั้งครรภ์ที่มีอาการแสบร้อนยอดอกโดยผู้เชี่ยวชาญที่มีความรู้ความชำนาญด้านสูติกรรม จำนวน 3 ท่าน จึงคาดว่าจะไม่เกิดผลข้างเคียงที่จะเกิดแก่ผู้ร่วมวิจัย ซึ่งในการเข้าร่วมวิจัยครั้งนี้จะเป็นไปตามความสมัครใจ โดยที่ท่านสามารถบอกเลิกการเข้าร่วมวิจัยนี้ได้ตลอดเวลา ซึ่งจะไม่มีผลกระทบใดๆต่อการดูแลรักษาทั้งสิ้น

การเก็บข้อมูลเป็นความลับ

ผู้วิจัยจะเก็บข้อมูลของท่าน ไว้เป็นความลับ จะเปิดเผยได้เฉพาะในรูปที่เป็นผลสรุปการวิจัยในภาพรวม การเปิดเผยข้อมูลต่อหน่วยงานต่างๆที่เกี่ยวข้องกระทำได้ในเฉพาะกรณีจำเป็นด้วยเหตุผลทางวิชาการเท่านั้น และในการวิจัยครั้งนี้ ผู้วิจัยจะไม่ระบุชื่อผู้ร่วมวิจัยลงในแบบบันทึกต่างๆ โดยจะใช้รหัสแทนผู้เข้าร่วมวิจัยแต่ละราย และผู้ที่จะสามารถรับรู้ข้อมูลเหล่านี้นอกจากผู้วิจัยและอาจารย์ที่ปรึกษาแล้วต้องได้รับความยินยอมจากท่านก่อน

ถ้าท่านมีปัญหาข้องใจหรือรู้สึกกังวลใจกับการเข้าร่วมในโครงการวิจัยนี้ ท่านสามารถติดต่อกับประธานกรรมการจริยธรรมการวิจัยในคน สำนักงานวิจัยคณะฯ อาคารวิจัยและสวัสดิการ คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี โทรศัพท์ 02-2011544

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APPENDIX J

HUMAN SUJECTS APPROVAL DOCUMENT

คณะแพทยศาสตร์โรงพยาบาลรามาธิบดี มหาวิทยาลัยมหิดล
๒๗๐ ถนนพระราม ๖ แขวงทุ่งพญาไท เขตราชเทวี กทม. ๑๐๔๐๐
โทร. (๐๒) ๒๐๑-๑๐๐๐

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Documentary Proof of Ethical Clearance
Committee on Human Rights Related to Research Involving Human Subjects
Faculty of Medicine Ramathibodi Hospital, Mahidol University

No MURA2014/640

Title of Project	The Effect of Heartburn Management Program on Frequency and Severity of Heartburn in Pregnant Women
Protocol Number	ID 11 – 57 – 38
Principal Investigator	Miss Darulrud Chuamuangsan
Official Address	Ramathibodi School of Nursing Faculty of Medicine Ramathibodi Hospital Mahidol University

The aforementioned project has been reviewed and approved by the Committee on Human Rights Related to Research Involving Human Subjects, based on the Declaration of Helsinki.

Signature of Secretary Committee on Human Rights Related to Research Involving Human Subjects	..... Prof. Duangrurdee Wattanasirichaigoon, M.D.
Signature of Chairman Committee on Human Rights Related to Research Involving Human Subjects	..... Prof. Pratak O-Prasertsawat, M.D.
Date of Approval	November 19, 2014
Duration of Study	5 Months

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APPENDIX K
THE TESTING OF THE NORMAL DISTRIBUTION

1. Control Group

One-Sample Kolmogorov-Smirnov Test

		maternal age	Family monthly income	Gestational age	Pre-pregnancy BMI
N		24	24	24	24
Normal Parameters[a,b]	Mean	30.79	36916.67	27.92	20.3004
	Std. Deviation	5.861	22426.53	2.020	2.25737
Most Extreme Differences	Absolute	.083	.204	.204	.176
	Positive	.075	.204	.204	.176
	Negative	-.083	-.115	-.162	-.116
Kolmogorov-Smirnov Z		.406	1.002	.998	.863
Asymp. Sig. (2-tailed)		.996	.268	.272	.445

a. Test distribution is Normal.

b. Calculated from data.

One-Sample Kolmogorov-Smirnov Test

		Frequency of heartburn before intervention	Frequency of heartburn after intervention	Severity of heartburn before intervention	Severity of heartburn after intervention
N		24	24	24	24
Normal Parameters[a,b]	Mean	2.58	1.63	1.50	1.00
	Std. Deviation	1.018	1.345	.511	.590
Most Extreme Differences	Absolute	.217	.224	.336	.333
	Positive	.217	.224	.336	.333
	Negative	-.159	-.154	-.336	-.333
Kolmogorov-Smirnov Z		1.062	1.095	1.647	1.633
Asymp. Sig. (2-tailed)		.210	.182	.009	.010

a. Test distribution is Normal.

b. Calculated from data.

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2. Experimental Group

One-Sample Kolmogorov-Smirnov Test

		maternal age	Family monthly income	Gestational age	Pre-pregnancy BMI
N		24	24	24	24
Normal Parameters[a,b]	Mean	29.29	28866.67	27.75	21.5821
	Std. Deviation	6.075	20055.81	2.345	2.28875
Most Extreme Differences	Absolute	.127	.198	.147	.112
	Positive	.104	.198	.147	.112
	Negative	-.127	-.149	-.123	-.094
Kolmogorov-Smirnov Z		.624	.969	.721	.549
Asymp. Sig. (2-tailed)		.831	.305	.676	.923

a. Test distribution is Normal.

b. Calculated from data.

One-Sample Kolmogorov-Smirnov Test

		Frequency of heartburn before intervention	Frequency of heartburn after intervention	Severity of heartburn before intervention	Severity of heartburn after intervention
N		24	24	24	24
Normal Parameters[a,b]	Mean	3.88	.79	1.63	.50
	Std. Deviation	2.346	.977	.495	.511
Most Extreme Differences	Absolute	.200	.291	.401	.336
	Positive	.187	.291	.272	.336
	Negative	-.200	-.209	-.401	-.336
Kolmogorov-Smirnov Z		.981	1.426	1.964	1.647
Asymp. Sig. (2-tailed)		.291	.034	.001	.009

a. Test distribution is Normal.

b. Calculated from data.

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APPENDIX L
THE RESULTS OF ADDITIONAL STATISTICAL ANALYSIS

The result of additional statistical analysis is presented in the following:

1. The frequency and percentage of the comparison the frequency and the severity of heartburn in the control group and the experimental group before and after the program.

2. The graph showed the tendency of the frequency and the severity of heartburn in experimental group from the beginning to the end of the program.

3. Test of between-subjects effects of the frequency of heartburn before entering the program on the frequency of heartburn after finishing the program.

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1. **The frequency and percentage of the comparison the frequency and the severity of heartburn in the control group and the experimental group before and after the program.**

Time evaluation	Control group		Experimental group	
	Number	Percentage	Number	Percentage
Frequency of heartburn after ≥ before the program	5	20.83	1	4.16
Frequency of heartburn after < before the program	19	79.17	23	95.83
Severity of heartburn after ≥ before the program	14	58.33	3	12.50
Severity of heartburn after < before the program	10	41.67	21	87.50

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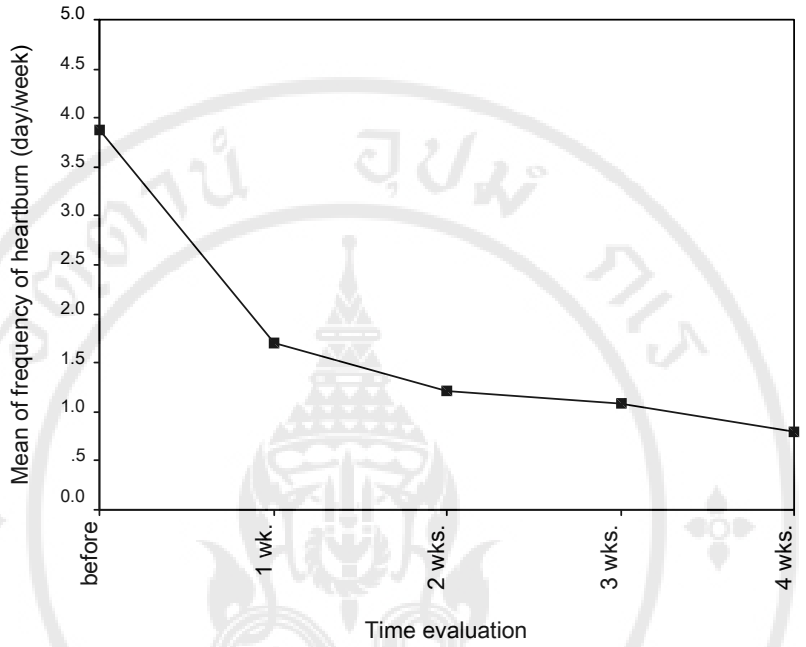
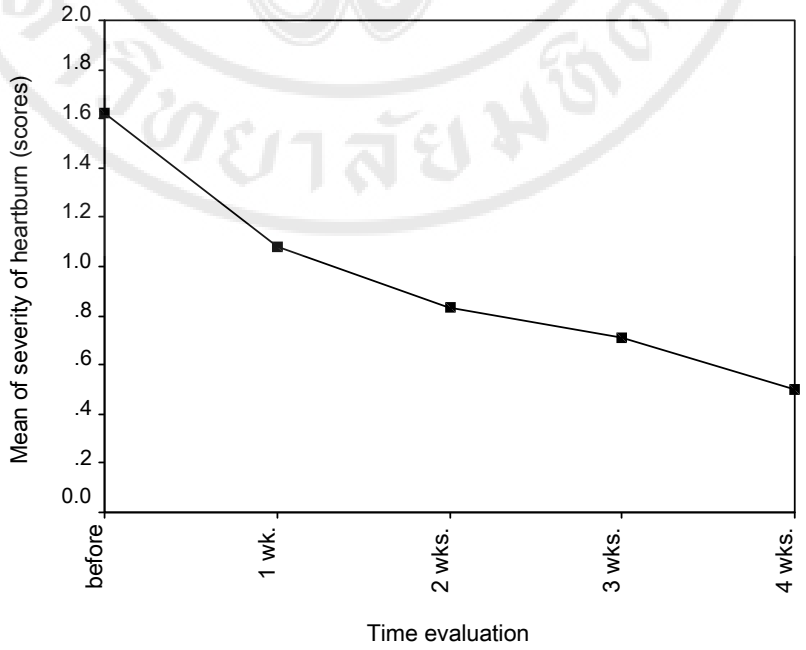
2. The graph showed the tendency of the frequency and the severity of heartburn in experimental group from the beginning to the end of the program.





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3. Test of between-subjects effects of the frequency of heartburn before entering the program on the frequency of heartburn after finishing the program.

Tests of Between-Subjects Effects

Dependent Variable: Frequency of heartburn after intervention

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	12.364[a]	2	6.182	4.671	.014
Intercept	5.127	1	5.127	3.874	.055
FREQ_BE	4.030	1	4.030	3.045	.088
GROUP	11.560	1	11.560	8.735	.005
Error	59.553	45	1.323		
Total	142.000	48			
Corrected Total	71.917	47			

a. R Squared = .172 (Adjusted R Squared = .135)

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BIOGRAPHY

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