Effect of Childbirth Education Program on Maternal Anxiety: A Randomized Controlled Trial Using Roy's Adaptation Model

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ABSTRACT

Background: Globally, 5.1 – 37.5 % of mothers suffer from anxiety during pregnancy due to adaptation problems. Childbirth education could enhance knowledge and skills to help mothers prepares to cope with adaptation. However, in Indonesia, the manner program provided following nursing theory as a framework has been absent.

Objective: To test the effectiveness of childbirth education program based on Roy's Adaptation Model on maternal anxiety

Methods: A randomized controlled trial using a computer random allocation block to allocate participants from five health centers in Yogyakarta has been performed. Pregnant women in the experimental group received a modified childbirth education program in four consecutive weeks comprised of lecturing, counseling, brainstorming, and practicing some essential skills for cope adaptation. A self-developed questionnaire was used to assess the demographic data set, Pregnancy-Related Anxiety Questionnaire-Revised was completed to measure the maternal anxiety during pregnancy. An independent t-test and ANCOVA were used to analyze the data.

Results: A total of 87 pregnant women were analyzed (experimental, n= 52, control, n=35), with a mean age of 23. 92 (SD = 1.89), and 29.14 (SD = 2.10), respectively. After the intervention, the score of maternal anxiety had significantly lower in the experimental group compared with the control group (p < .001). In the T-test analysis, the demographic variables were not related to maternal anxiety.

Conclusion: Based on the findings, a modified childbirth education program focus on adaptation change based on nursing theory was effective to decrease maternal anxiety during pregnancy. However, what the participant perceived in the prenatal education program is one of the salient limitations in this study.

1. Introduction

As multifaceted changes, pregnancy requiring adaptations that are not only physical, but also psychosocial, marital, spiritual, and financial (Chang et al., 2015). Consequently, difficulty adapting to those changes resulted in anxiety. Even though it is a common and normal response, it can become mental health problem (Deklava et al., 2015; Goodman, Guarino, Chenausky, Klein, Prager, Petersen, et al., 2014; Lorenc et al., 2014; Maxson et al., 2016; Wenzel, 2011). According to one study, only

seven percent of expectant women do not suffer from anxiety during pregnancy, particularly in the last trimester (Madhavanprabhakaran et al., 2015). About 5.1 – 37.5 % of mothers experience anxiousness during pregnancy which can affect physical and mental problems. In high-income countries, most studies on maternal anxiety have been targeted. In low-and-middle-income countries (LMIC) mental health issues have remained a key focus of research and healthcare. The prevalence of maternal anxiety in Asia has been recognized by about 20% (Roomruangwong & Epperson, 2011). In Indonesia, it is reported 28.7% of pregnant women suffer anxiety during the three last trimesters. This may due to many factor such as level of education, level of economic status, parity, and maternal health status (Kahyaoglu Sut & Kucukkaya, 2020).

Pregnant women with high levels of anxiety are at increased risk of adverse perinatal outcomes (Abasi et al., 2012; Clemens & Virginia, 2014; Yuksel et al., 2013) including postpartum depression, preterm birth, low birth weight (O'Donnell et al., 2016), and fetal growth restriction which in turn, are risk factors for impaired cognitive and social development children (Buss et al., 2011; Fishell, 2010; Jiang et al., 2016; O'Donnell et al., 2012). Another negative effect of anxiety during pregnancy is the effect on sleep quality (Jamalzehi et al., 2017). Anxiety can lead to a problem such as sleeping disturbances (Skouteris et al., 2009), nightmare (Furber et al., 2009), and fatigue (Andersson et al., 2012). Anxiety during pregnancy may manifest as maladaptive responses to stress, such as denial, self-blame, and self-distraction (Gourounti et al., 2013). Anxiety due to fear of specific events, such as labor, may also contribute to mood swings, panic, and discomfort about the feeling of having a baby living inside (Bayrampour et al., 2016).

According to Roy Adaptation Model (RAM), ineffective defense mechanisms in one or more of the critical modes affected a person's adaptation level. This adaptation level, will, in turn, impact the individual's ability to respond effectively to stimuli (Roy, 2009). Roy uses stimuli as a way to describe the pregnant woman's environment, such as learning resources, partners, and social support. There are two reasons why using Roy's Model approach as a framework to develop the childbirth classes is essential in this study. First, nurses and midwives play major roles in health-promotion activities. To achieve this critical goal of health promotion, the nurse and midwives needs an accurate and complete data base. At present in Indonesia, there is scarce concept of childbirth education class which is applied the Roy's Adaptation Model to provide the intervention (Bayrampour et al., 2016; Berthelot et al., 2020; Comaskey et al., 2017). Using this model approach, the appropriate contents and teaching methodology in the prenatal education will be available as the practice-based practice. Second, during pregnancy and preparation for childbirth, pregnant women and spouse seek out information from various source. Nurse and midwives, in both professional and personal, encounters, also encourage and interact daily with pregnant women and husband. Childbirth education classes are one kind of resource for helping expectant women prepare to adapt to the changes that may lead them to anxiousness (Larsen & Plog, 2012). Through the childbirth education programs, midwives could enhance the mother's physiological model to increase their adaptation during the transition by providing sufficient information and insight about pregnancy such as the education of anatomical and physiological adaptation, which in turn, can help the mother to reveal their anxiety during pregnancy (Harpel, 2008). Many kinds of literature mention the specific intervention in the prenatal education class could reduce maternal anxiety, particularly during the third trimester such as yoga, Coping Anxiety through Living Mindfully (CALM), and hypnotherapy (Baxter et al., 2008; Goodman, Guarino, Chenausky, Klein, Prager, & Petersen, 2014; Rasouli et al., 2019; Tragea et al., 2014). The effectiveness of Roy's Model to promote maternal mental health has been tested in different project methods (Amanak et al., 2019; Fawcet, 2006; Isbir & Mete, 2010; Sercekus & Mete, 2010). In Indonesia, childbirth education programs were provided by government trough health centers at free of cost. The evaluation of the programs to address maternal anxiety have been conducted (Eugenie & Napitupulu, 2014; Kristianingsih & Suryanti, 2019; Lestari et al., 2019; Naharani et al., 2018; Sumiyarsi et al., 2018), however, the method approach are insufficient and the theory guideline are remain absent. Therefore, the first ever study on the effectiveness childbirth education program on maternal anxiety based Roy's Model as the conceptual framework, prompted to be conducted (Asa et al., 2016; Eugenie & Napitupulu, 2014).

2. Methods

2.1. Study Design and Setting

This is a randomized controlled trial. All primigravida women who visit the five health centers in Yogyakarta which have a regular standard childbirth education program were approached. Using a computer random allocation block (Saghaei, 2004), respondents were allocated to two groups: those who attended modified childbirth education program and those who attended standard childbirth education program. The allocation list using a 4,6,8 sequence. Considering an α of 0.05, effect size = .25 (Funder & Ozer, 2020), power= .80, the sample size 49 women in each groups were resulted. Given the possibility of dropouts during the study, we recruited 61 women to each group".

2.2. Participants

The target population was pregnant women who attend the antenatal care at health centers in Yogyakarta which provide the standard childbirth education program. Participants had to obtain the following criteria: (a) first time pregnancy, (b) age 25 to 35 year, (c) more than 29 weeks' gestation, (d) singleton pregnancy. Exclusion criteria: (a) experience complications during pregnancy, (b) have no complete attend our program, (c) more than 36 weeks of gestation. We invited husband to participated join the class during the program in this study.

2.3. Data collection procedures

Each center was managed by the same researcher and research assistants to recruited eligible participants. Two research assistants were participated in a one-day training session to discuss the aims, procedures, and protocols of the study. After the ethical permission was obtained from the Institutional Review Board of 'Aisyiyah University of Yogyakarta, the researcher and assistants were distributed flyers to the mothers who are potential participants while they are waiting their turn to enter the antenatal care clinic. We have explained the purpose of the study to all potential participants, the benefits of participation, and the low risk of harm (Ghaedrahmati et al., 2018; Holden et al., 2019; Lewis et al., 2015). Potential participants also have been allowed to ask questions about the study. Once a participant agrees, the researcher or a trained assistant will ask them to fill out the informed consent form and include their cell phone number. The diagram of data collection was described in the Fig. 1 below.
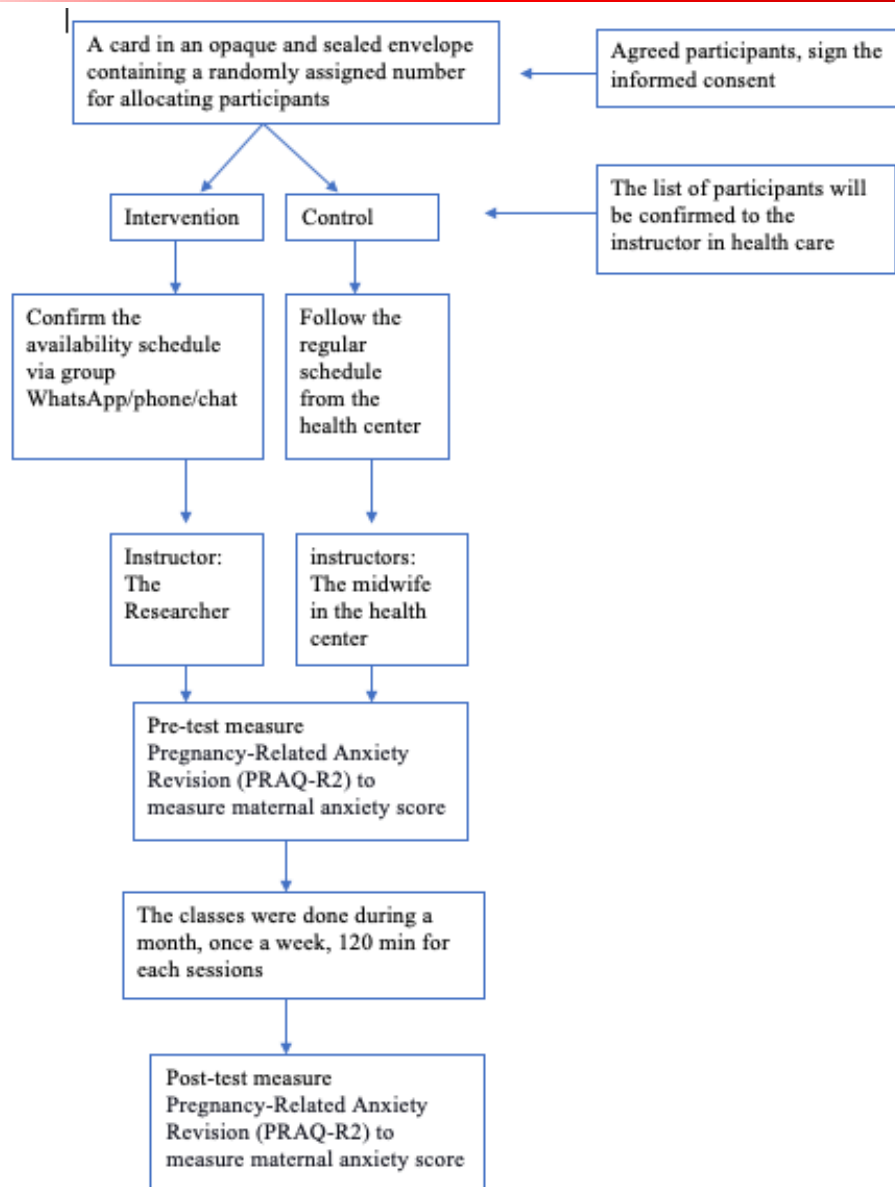
Fig. 1. Sampling Diagram

We applied two instruments in this study; the respondent's demographic characteristics to obtained personal information and the Pregnancy-Related Anxiety Revision (PRAQ-R2) to measure maternal anxiety. The mothers were asked to complete the study questionnaire to establish a baseline measurement for two instruments. After four weeks of classes, the participants were self-administered the same questionnaire again without the demographic portion. Completing the questionnaire was estimated 15 to 20 minutes. Demographic characteristics information included the mother's education level and occupation. The PRAQ-R2consisted of 34-items developed by Van Den Bergh. The scores on each item range from 1 (definitely not true) to 5 (definitely true) (Huizink, A. C., Mulder, E. J., Robles de Medina, P. G., Visser, G. H., & Buitelaar, 2004). The 10-items consist of three subscales: items 1, 2, 6, and 8 are related to "fear of giving birth," items 4, 9, 10, and 11 are connected to "worries about bearing a physically or mentally handicapped child," and items 3, 5, and 7 are related to body image or "concern about own appearance. The minimum and maximum total scores are 11 and 55, respectively, with the assumption, more scores, more anxiety in pregnancy. The previous researcher assessed the reliability of the scale using Cronbach's Alpha, ranged from .75 to .84. The translation and back-translation procedure conducted by another scholar resulted from the English version of PRAQ-Q2. Comprised of four steps (forward translation, back-translation, committee review, and expert judgment using Content Validity Index), we administered the translation version to 87 pregnant

women for internal consistency assessment. The Cronbach's alpha level of pretest and posttest were acceptable ($\alpha = .83$, and $\alpha = .93$, respectively).

Intervention group

The researcher prepared the curriculum to encompass the four-mode of adaptation explained in RAM: physiological, self-concept, role function, and interdependence. The content of the counseling session included the strategies for coping with stress, plans for effective communication with one's husband and others, share experiences and expectations regarding feelings, pregnancy, and birth. Simulation and practice sessions included relaxation, maternal-fetal attachment skills, comfort measures, childbirth position using the birth ball, bathe and wrapping the baby, and breastfeeding position. The participants in this group are women and husband. The primary investigator (PI) provided this class for couple in the experimental group in a 180-minutes session held during four consecutive weeks. PI conducted the class at the antenatal care laboratory of 'Aisyiyah University of Yogyakarta due to the capacity and the well-equipped instrument reason. Thus, there were five intervention group classes. Since it was impossible to recruit enough participants to run five types simultaneously, the researcher team conducted two courses simultaneously, repeating the recruitment and teaching process once the number of participants fulfilled. The distance from the recruiting place to the intervention setting up to 5 km. During the class, the participants provided the suggestion for the class revision based on their need in term of material, methodology lecturer, skill practicing they wish to learn.

Control group

The control group classes were conducted at the health centers (*puskesmas)* they recruited, not at the university. The facilitators of the control groups were midwives who are already providing prenatal education classes at the *puskesmas*. The courses followed the government curriculum, consisting of three types per month, and does not compulsory to invite husbands to participate. However, in this study, participants in the control group have four classes over one month to better match the program of the intervention group. The material for the standard curriculum includes anatomical and physiological changes during pregnancy, pregnancy care, birth, and postpartum care. The classes also address family planning after giving birth, newborn care, preventing infectious disease, and procedures for obtaining a birth certificate. The midwives also discuss and debunk unhealthy local myths, beliefs, and cultural practices surrounding pregnancy, childbirth, and postpartum. The participants in this group are women and husband. In this study, the control group participants have attended standard childbirth education classes during the same period as the intervention group. Again, the types followed the government curriculum, which consists of three courses per month. However, in this study, participants in the control group have four classes over one month to better match the program of the intervention group. The control group has a half hour to fill out the questionnaires and a half hour for feedback and discussion for the fourth class. Then the researcher and assistants have provided the control group participants with a condensed two-hour class of relaxation techniques, comfort measures, and maternal-fetal attachment activities. The comparison program between the experimental and the control group as listed in table 1.

Table 1. Comparison childbirth education program between experimental and control group

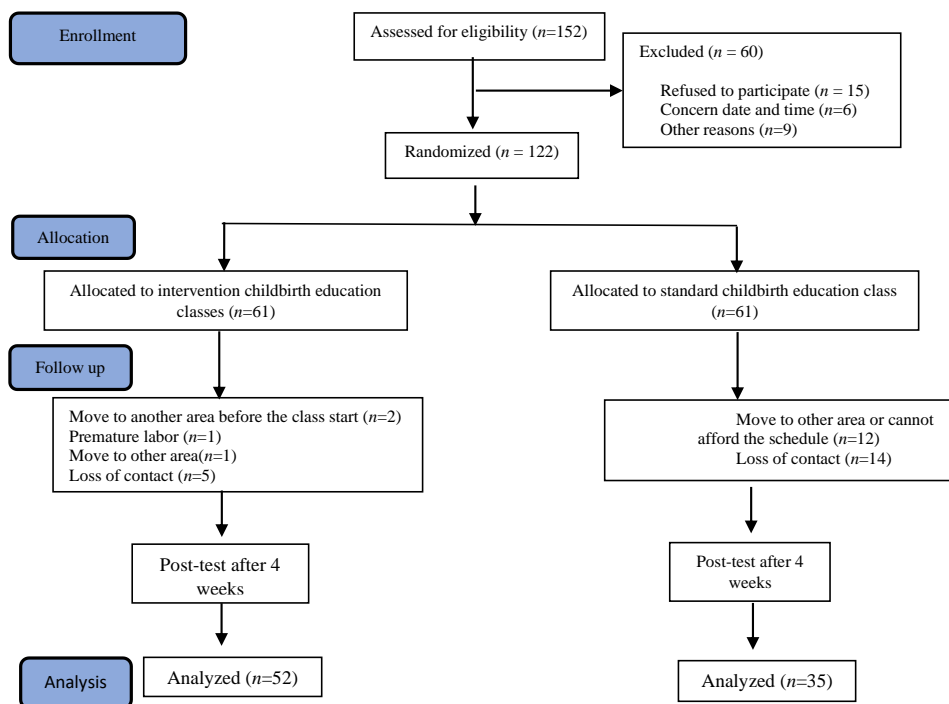|	Experimental group	Control Group
Content	Anatomical and physiological changes during pregnancy and birth, maternal-fetal attachment skills, parenting skills, comfort measures, childbirth positions, pregnancy, relaxation exercise during pregnancy and labor, and couples communication issues.	Anatomical and physiological changes during pregnancy, pregnancy care, birth, and postpartum care, family planning after giving birth, newborn care, preventing infectious disease, and procedures for obtaining a birth certificate.
Learning method	Lecturing, round table discussion, demonstrating, practicing, and watching the video. Following up the practical using group online discussion.	Lecturing and discussing
Hour	3 hours/session	2-3 hours/session
Instructor	Researcher	Midwives in the health center
Participants	Mother and Husband Relatives	Mother
Place	Childbirth education room	Health center

2.4. Data analysis

The data were analyzed using Statistical Package for Social Science (SPSS) 20.0 program. A T-Test was applied to compare the quantitative data to test the effectiveness of the childbirth education program on maternal anxiety.

2.5. Ethical consideration

This study obtained ethical approval from 'Aisyiyah University of Yogyakarta (No.1303/KEP-UNISA/XI/2019), and its clinical trial has been registered (NCT047s59118). Furthermore, the researcher strictly followed the principal ethical code to conduct the experimental study, including the confidentiality of the information from respondents who the researcher and two research assistants reassured.

3. Results/Findings

The participants for this study drawn from five public health centers in Yogyakarta, Indonesia; Mlati II, Jetis Kota, Mantrijeron, Kraton, and Godean I. In total, 87 participants consisting of 52 mothers in the experiment group and 35 mothers in the control group (see Fig. 1) participated in this study. In such cases, some participants dropped out of the program about 29%. Thus, the final analysis after 4-weeks intervention resulted from

Fig. 2. CONSORT flow chart

We presented the baseline assessment for the demographic information such as a gestational week, education level, and occupation between the control and experimental group in table 2. There was no significant difference in mean score for the mother's education level between the two groups. However, there was a considerable difference in the mean score of the couple's age, gestational week, and mother's occupation, and husband's education level (*p*<.001) in the experimental and the control groups. The participant's age ranged from 20 to 35 years old, mean (*SD*)=23.92 (1.89) in the intervention group and 20 to 28 years old, mean (*SD*)=28.40 (3.07) in the control group.

Table 2. The comparison of the demographic characteristics between the experimental and control groups

	Wife				Husband			
Characteristics	*Experiment (n=52) n(%)*	*Control (n=35) n(%)*	*t/χ2*	*p*	*Experiment (n=52) n(%)*	*Control (n=35) n(%)*	*t/χ2*	*p*
Age (M□SD)	(23.92□1.89)	(29.14□2.10)	-12.08[a]	<.001	(26.75□2.40)	(30.86□2.20)	-8.11[a]	<.001
Gestational week(M□SD)	(29.83□1.45)	(31.04□1.80)	-.3.45[a]	<.001	NA	NA	NA	NA
Education level								
Elementary	18(34.6)	6(17.1)	3.85[b]	.146	1(1.9)	5(1.9)	11.33[b]	<.001
High school	24(46.2)	23(65.7)			42(80.8)	17(48.3)		
College	10(19.2)	6(17.1)			9(17.3)	13(37.1)		
Occupation								
Employed	36(69.2)	22(62.9)	14.94[b]	<.001	52(100)	35(100)	NA	NA
Unemployed	16(30.8)	13(37.1)			0(0)	0(0)		

a= Chi Square; b= t test; SD= standard deviation

The baseline of pretest scores of maternal anxiety calculated using an *independent T-test*, and there was a significant difference mean score (*p < .05)* in the experiment group (*M±SD= 28.23±7.70; n=52)* and the control group (*M±SD= 35.97±6.92; n=35).*

3.1. The effect of the childbirth education program on the maternal anxiety score

Table 3 described the effect of a childbirth education program on maternal anxiety. The intervention group had a lower maternal anxiety score (-16.67) than the control group. Based on the table, the increase of one point pretest maternal anxiety score would increase 0.19 points off the posttest maternal anxiety. Demographic variables such as a gestational week, couple's age, couple's education level, and couple's occupation were not related to the maternal anxiety level.

Table 3. The effect of childbirth education program on the maternal anxiety (*n*=87)

Variable	B	SE	t	P	95% CI
Intercept	43.47	15.22	2.86	.006	13.11~73.82
Group (E vs C)	-16.67	1.94	-8.58	<.001	-20.53~-12.80
Maternal age	-0.49	0.33	-1.47	.145	-1.15~0.17
Gestational week	0.17	0.28	0.60	.555	-0.38~0.71
Husband's age	0.13	0.28	0.46	.648	-0.42~0.67
Wife's education (ref: College)					
Elementary-junior	-0.42	1.51	-0.28	.784	2.60~-3.43
High school	0.68	1.36	0.50	.616	-2.01~3.38
Husband's education (ref: College)					
Elementary-junior	1.87	2.09	0.89	.375	6.03~-2.30
High junior	-0.62	1.22	-0.51	.614	1.81~-3.04
Wife's occupation: (ref: Unemployed)					
Employed	-2.10	1.19	-1.77	.081	0.26~-4.47
Baseline :					
Maternal anxiety	0.19	0.0	2.290	.025	0.36~0.03

Note: E= experimental; C = Control; CI= Confidence Interval; SE= Standard Error; ref =reference

4. Discussion

We found some basic issues in this study. First, the socio-demographic and obstetric features issue. Those two data are to be similar in the experimental and control groups. However, since the attrition rate relatively high, the final demographics and obstetrics comparison found the differences. Many participants from the control groups lost. In this group, midwives set up the schedule in the health center. However, we have established the effort to prevent the possibility high attrition rate such as, in the experimental group, the plans were set up together by PI and the respondents. The participants could reschedule the class according to their availability time. Thus, it gained the sustainability of the participant's presence in the experimental group. Consequently, the presentation of the employed mother was lower in the control group than in the experimental group. In term of mother's age, the loss reduced number of the participants in the control group were higher than in the experiment group. Some young expectant mothers decided to stop joining the program in the control group. They might move to another area or hometown to seek psychological support from their family when delivering the baby. Interestingly, these spouses of young expectant mothers also have the same age as they. Therefore, the majority of the younger husband has discontinued the program in the control group as well. We also provided the compensation for each participants in each group to minimize the attrition rate in two groups.

Next, we found the baseline of the maternal anxiety score was significantly different between the two groups. Thus, mothers in the experimental group mostly perform a low pregnancy anxiety score than in the control group. The possible reason is majority participants in the experimental group are younger than in the control group. Therefore, we applied appropriate statistical analysis to test the data to deal with this issue. The result of the covariate analysis showed that mothers who participated in the experimental group had a lower anxiety level score than the mothers who participated in the control group (*p*<.001). In addition, the result of the t-test analysis showed that the posttest score of anxiety mothers who participated in the intervention group had decreased significantly than the pretest score. This finding result, echoing by previous research finding in Iran (Bastani et al., 2006). The primary goal of Roy's Model is to promote humans to have positive adaptation to the stimuli. In this study, the mother learned and prepared for her upcoming childbearing process through the various learning

methods and topics. The program was offered for four weeks and lasted for 120 minutes for every session. In addition, to address maternal anxiety, we provide some relaxation techniques to release such tension due to discomfort during pregnancy and labor preparation. Thus, lack of awareness and distress of the unknown during pregnancy and childbirth that can lead anxious as an in adaptive response can be avoided by mothers, likewise reported in Turkey (Yikar, 2019). The researcher considered arranging the material outline according to the participant's suggestion. As adopted from the guidelines, the learning method also has been modified according to the design. The researcher conducted lecture methods for some basic knowledge about pregnancy, labor, and delivery. While practicing practice was worked for some skills and discussing was achieved for problems solving. The researcher explored the couples thoughts and feelings and their expectations of their partner during discussion sessions. Based on that, the researcher may suggest that the health policy maker consider that the standard prenatal education program needs to be modified. The variance variation of the class learning method also needs to take into account. As the facilitator in the prenatal education program, the midwives expected to be more innovative to modified the attractive class to be beautiful. As the theory-based intervention, this finding envisioned providing evidence to enhance the effectiveness of the modified childbirth education program. Compare with the standard childbirth education program; We emphasized the modified classes on the variance of the learning methods based on the topic and learning outcomes.

However, We should note some limitations in this study. First, each class lasts for have three hours per session for each category. This duration seems too short for practicing and discussing the session and results in an overtime session. In contrast, for the lecturing session, the course seems too long. Therefore, the researcher would suggest adjusting the duration based on the topic and the learning method but still has the same total hours as the guidelines (12 hours). Second, the researcher only invited expectant mothers with normal pregnancies and measured their outcome variables; therefore, for the subsequent study, we may be considered to ask pregnant women with complications to test the efficacy of the prenatal education program on the pregnancy outcomes. Third, since the study setting for the intervention and the control group is different, the following study needs to consider the twin study using a double or triple blinded method to prevent bias that may affect the result. Finally, the next researcher also needs to consider the correlation of the variable outcomes to the postnatal event. Therefore, a longitudinal study needs to be conducted.

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