Effectiveness of the Preterm Labor Prevention Program for High-Risk Pregnant Women: A Randomized Controlled Trial

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Abstract: Preterm labor significantly impacts premature birth, influencing infant development and health outcomes. This randomized controlled trial aimed to develop and test the effectiveness of the Preterm Labor Prevention Program on primary outcomes (knowledge, attitudes, self-care practices) and secondary outcomes (preterm labor, preterm birth rates). Sixty-six high-risk participants aged 15-49 attending antenatal care clinics in Northeastern Thailand were selected using multi-stage random sampling. They were randomly assigned to either the experimental group (n = 32) receiving the Preterm Labor Prevention Program in addition to routine care or the control group (n = 34) receiving routine care. Data collection employed questionnaires on knowledge, attitude, self-care practice, preterm labor, and preterm birth rates. Data were analyzed using one-way repeated measures ANOVA for knowledge, attitudes, and self-care practice scores across three-time points at baseline before the intervention, immediately and four weeks after program completion, and chi-square tests for comparing preterm labor and premature birth rates across groups.

Results indicated that the mean score of knowledge, attitude, and self-care practice in the experiment group was significantly increased over time immediately and four weeks after program completion and significantly higher than that of the control group at both time points. Furthermore, the incidence of preterm labor and the preterm birth rate in the experiment group were 6.25% and 3.10%, respectively. However, the incidence of preterm labor and the preterm birth rate in the control group were equal at 20.60%. Nurses and midwives can apply this program to increase knowledge, more positive attitudes, and practice to reduce preterm labor and preterm birth in high-risk pregnancies, but first, testing of the program is required with an increased number of participants

Keywords: High risk, Pregnant women, Preterm birth, Preterm labor, Prevention program, Randomized control trial

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Introduction

Preterm labor leading to premature birth is a serious health problem that begins before 37 weeks of pregnancy.[1] A report by United Nations agencies and partners indicates that 13.4 million newborns were delivered prematurely in 2020, with nearly one million newborns dying from premature birth-related complications.[2] In 2021, premature birth occurred in approximately one out of every ten pregnancies at gestational ages under 37 weeks in the United States.[3] Internationally, the premature birth rate was 4-16% of newborns in 2020.[3] Moreover, the majority of

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preterm births occur in southern Asia and Sub-Saharan Africa.[2] In 2021, Thailand's annual incidence of preterm birth was 12.5%[4] with reports of 10.83% in some places,[5] which is considered high. Meanwhile, Thailand's 12th National Health Development Plan (2017-2021) determined the threshold for newborns weighing under 2,500 grams not exceeding 7%.[6] A report between 2021 and 2022 estimated underweight birth rates at 6.39%[7] and 6.46% of all live births, respectively.[8] Furthermore, two in three births were premature,[7] so preterm birth must be recognized as an important factor affecting low birth weights.

The effects of premature birth emerge in both pregnant women and newborns. Infant complications such as respiratory distress, brain hemorrhage, intestinal infection, other severe infections and brain conditions occur due to organ immaturity.[9] Premature birth is a major cause of low birth weight, contributing to 16% of infant deaths.[3] Low birth weight increases the risk of obesity, diabetes, and other chronic diseases in adulthood.[2] Annually, 15 million babies worldwide are born prematurely, equating to an 11% global preterm birth rate. This results in 1 million child fatalities before the age of 5, establishing preterm birth as the foremost cause of child mortality, attributing to 18% of under-five deaths and as much as 35% of neonatal fatalities (< 28 days).[10] Many surviving preterm babies endure lifelong disabilities, encompassing learning difficulties as well as visual and auditory impairments.[2,10]

Prevention of preterm labor and preterm birth is necessary to lessen its impact on families and the health care system. Previous studies indicate many factors associated with preterm labor. Those factors are maternal physical health,[11] ages of < 20[12] or > 40 years,[13] history of preterm birth,[1,3] severe anemia,[12,14] multiple pregnancies,[5,12] body mass index,[11] malnutrition,[15] preeclampsia,[5,16] inadequate antenatal care (late ANC and follow up < 4 times),[5,12] socioeconomic status,[17] non-white ethnicity,[18] maternal mental health,[11] stressful life situations, such as domestic violence, death of a close family member,[1] marital conflict,[1] and workplace issues and home environment problems.[11] In addition, the changing lifestyles of pregnant women, such as working outside the home and commuting long distances, smoking or fast-paced lifestyles, cause increased stress.[1,3,19] Modern pregnant women have become more advanced in maternal age, and assisted reproductive technology is used, often leading to twin pregnancies, which can cause preterm birth.[19]

Some of these above factors are beyond control or avoidance. Nonetheless, thoroughly understanding these factors is invaluable in designing effective prevention programs. Addressing factors associated with self-care behavior among pregnant women at risk for preterm labor is imperative. Modifiable factors influencing self-care include knowledge, perception, access to credible resources, and family support.

Prior intervention studies have elucidated that promoting knowledge and perception plays a pivotal role in fostering self-care practices for preventing preterm labor pain.[20-21] Additionally, family support plays a critical role in facilitating knowledge among high-risk pregnant women.[22] An intervention study aimed at preventing preterm labor and premature birth revealed that a comprehensive approach involving knowledge and self-care education for pregnant women at risk of preterm birth,[20-23] the dissemination of knowledge through mobile and media applications,[20-24] the expansion of communication channels,[24] including telephone monitoring,[20,22] regular follow-up, monitoring symptoms and uterine contraction and family support[22] had the potential to mitigate the occurrence of preterm birth. Following previous studies, it is evident that factors influencing self-care behaviors among high-risk pregnant women encompass critical elements such as robust social support networks, the aptitude to recognize the onset of premature labor pain, and a comprehensive understanding of issues related to premature birth.[25-28]

It is essential to acknowledge that the literature regarding preterm labor prevention programs is relatively sparse. Furthermore, the applicability of existing research

to the specific context of pregnant women at risk remains limited. Consequently, premature labor continues to prevail at a notably high rate. Hence, we were interested in developing a tailored preterm labor prevention program and testing its efficacy on primary outcomes, knowledge, attitudes, and practice, as well as on secondary outcomes, the reduction in preterm labor rates and preterm birth rates among pregnant women with high-risk factors.

Literature Review and Conceptual Framework

This study used the Health Belief Model[29] (HBM) to develop the Preterm Labor Prevention Program (PLPP) for high-risk pregnancies to prevent preterm labor. The risk factors for preterm delivery include maternal age, pre-pregnancy body mass index, anemia, urinary tract infection, maternal education, socioeconomic status, history of previous preterm birth, inter-pregnancy interval, smoking, hypertensive disorder, diabetes mellitus, number of antenatal care visits and maternal height.[1,3,5,11-16,30-34]

According to the HBM,[29] health behavior is influenced by the person's health-related beliefs or perceptions and the means for preventing disease.[35] The foundation of the HBM is the ideology that health belief modification is vital to successful and sustainable changes in behavior. The four main components of the HBM are perceived susceptibility (risks, which are based on the person's perceived readiness for adaptation to health-promoting behaviors); perceived seriousness (a person's beliefs concerning the hardships of having a disease and their impact on the quality of life); perceived benefits (personal opinions concerning a health-promoting behavior aimed at minimizing the impact of disease); perceived barriers to action (a person's assessment of obstruction to engagement in a new health-promoting behavior). Beyond its four main components, the HBM recommends cues to action that will facilitate a person in adapting to health-promoting behavior. These cues can be categorized as internal (history of disease) or external (media, healthcare providers).[29]

Previous studies showed the factors related to preterm labor to be perception, knowledge and social support.[25-28] Perceived susceptibility, perceived seriousness, perceived benefits and perceived barriers to action concerning preterm birth positively correlate with preterm prevention behavior with statistical significance.[26-28] Social support combined with promoting preterm labor perception and knowledge can also co-predict the preterm labor prevention self-care behaviors of pregnant women.[25]

Prior studies applied the HBM to determine the perceived risks and seriousness of preterm birth, as well as perceived benefits of and barriers to preventing preterm birth, revealed that there were factors associated with self-care behaviors in preventing preterm labor.[26-28] Knowledge and social support have been found to reduce preterm labor.[25] Moreover, some researchers used the HBM for health education, such as successfully preventing urogenital infections in pregnancy.[36] Similarly, promoting perceived seriousness based on health-related knowledge and information can be facilitated by focusing on personal beliefs concerning the hardships of having a disease.[20,23] Regardless, perceived risks, seriousness and benefits alone are unlikely to trigger behavior change. Therefore, obstacles must be minimized in combination with education concerning easy access to education and counseling, which can be provided through informative applications and/or online/phone consultation, leading to the successful prevention of preterm labor in pregnant women in high-risk groups.[20,21] Furthermore, family support can facilitate overcoming the barriers to prevent preterm labor. Such support encompasses various elements, including social backing, regular antenatal check-ups, educational guidance, motivational encouragement and mental support.[22,37] Prior research has indicated that social support, awareness of preterm labor, and knowledge

about preterm labor collectively promote prevention through self-care behaviors among high-risk groups.[26,28] Furthermore, telephone-based condition monitoring and continuous monitoring of uterine contractions are effective in preventing preterm labor.[26]

Pregnant women at high risk of preterm labor and premature birth must be concerned about risks and self-care to prevent preterm labor. At the same time, healthcare providers must reduce barriers to self-care, which involves promoting health education and enhancing family support. Thus, this study aimed to develop the PLPP and test whether focusing on increasing perception about the susceptibility, seriousness and benefits of preventing preterm labor will increase knowledge of self-care, attitude and practice, resulting in reducing preterm labor and the preterm birth rate. The following hypotheses were set:

1. The experimental group receiving the PLPP would have a mean score of knowledge, attitude, and self-care practice significantly increased over time immediately and four weeks after program completion and significantly higher than that of the control group at both time points.

2. The experimental group would have lower preterm labor and birth rates than the control group.

Methods

Design: This study was a single-blinded randomized controlled trial (RCT). The writing of this report adhered to the CONSORT 2010 Checklist for essential information inclusion in RCT design.

Study Setting: This study was conducted across two distinct antenatal care clinics within separate hospitals in different provinces in the northeastern region of Thailand. The participants were high-risk pregnant women under the care of one of the above antenatal clinics.

Sample: The sample size was determined using the G*Power software (Version 3.1.9.4) and the statistical significance was set at .05, power of test at 0.80, and effect size at 0.49 (Cohen's f) according to Phetcharak et al.,[26] who studied the relationship between preterm labor and the prevention of premature birth, which found a positive statistically significant correlation between maternal perception and the occurrence of preterm labor ($r = 0.433$, $p < .001$). The calculations yielded a sample size of 25 in each group. Subsequently, an additional 20% was factored in to accommodate potential dropouts during the program, making the required sample size 30 participants per group. Inclusion criteria were 1) being currently pregnant, aged 15-49 years, gestational ages of between 20-24 weeks at the first program session; 2) being at least one risk of preterm labor based on the Preterm Labor Risk Assessment Form;[34] 3) having family, relatives or friends who were available and willing to provide care during pregnancy; 4) being convenient access to online information; 5) being able to comprehend and communicate in Thai; 6) having a smartphone to communicate and watch video clips; and 7) willing to participate in the study. The exclusion criteria were pregnant women with severe complications during pregnancy requiring close monitoring by an obstetrician, such as heart disease, severe hypertension, and thyrotoxicosis.

Sampling: Steps in the selection of the participants were as follows: 1) stratified random sampling was used to select four provinces in Northeastern Thailand based on annual birth rates: Group 1 ≥ 20,000 per year (1 province) and Group 2 <20,000 per year (3 provinces); 2) random sampling selected one province from group 1 and one province from group 2; 3) one general hospital in each province was chosen via simple random sampling; 4) sample sizes for each hospital were determined through proportional stratified random sampling, taking into account the birth rates in the two provinces; 44 participants were from Hospital 1. and 24 participants were from Hospital 2; 5) the participants meeting the inclusion criteria were chosen randomly from the antenatal clinics of each hospital. Then, potential participants were matched based on

age range, gestational age, gravida status and preterm labor history before undergoing random selection. Participants were assigned randomly to either the experimental group (n = 34) or the control group (n = 34). Additionally, each participant was required to select family members who assumed the role of caregivers and demonstrated their willingness and capacity to engage actively in the program. This study encompassed an 8-week duration, during which a cohort of high-risk pregnant women was closely monitored. Following the initial four weeks of the program, 66 participants underwent comprehensive analysis. Of these, 32 individuals were in the experimental group, while the remaining 34 were in the control group. Each of the two hospitals had different schedules for service provision, but an equal number of participants were allocated to the experimental and control groups. **Figure 1** illustrates the participant flow.

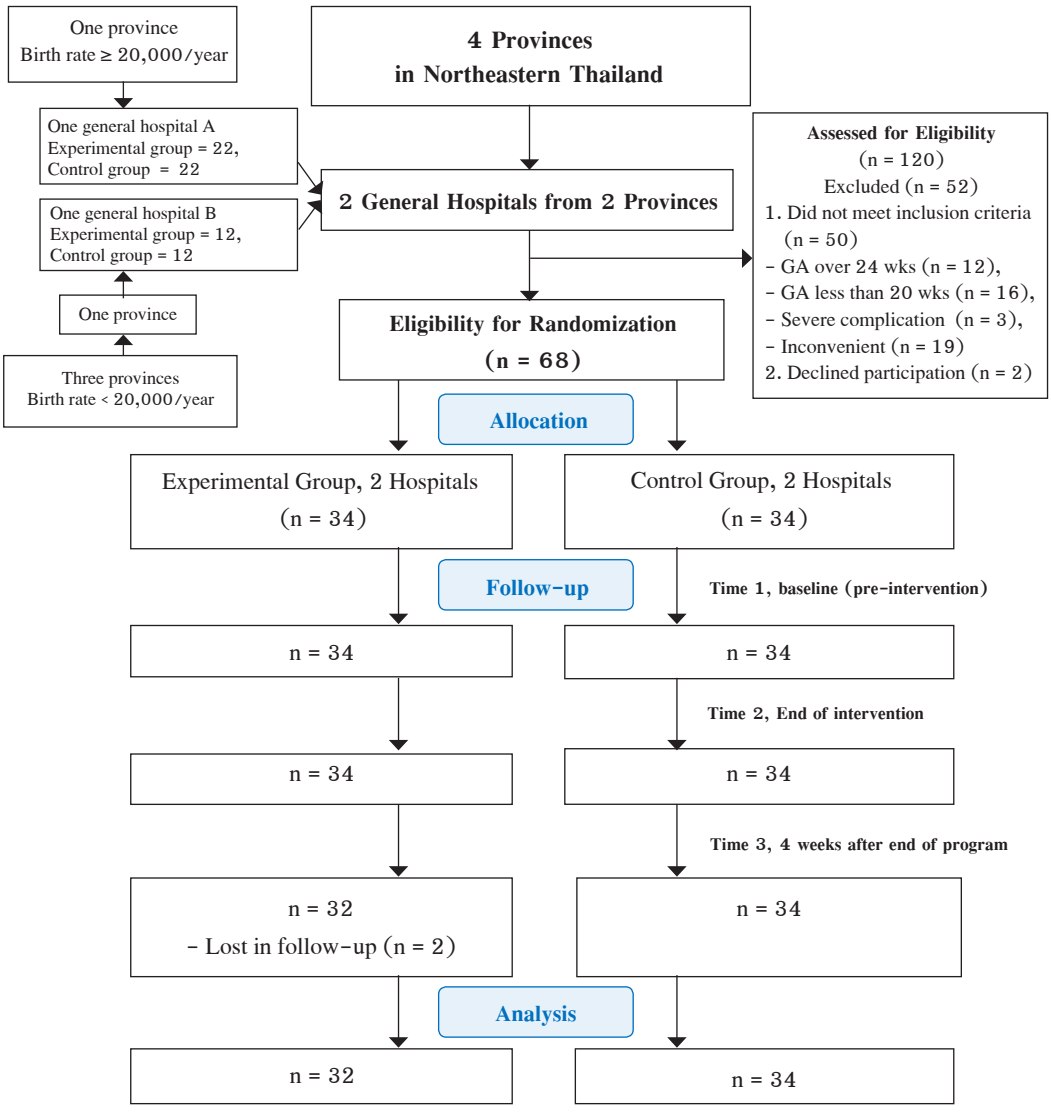

Figure 1. Flow diagram of the participants in the study

Ethical Considerations: The Ethical Review Sub-Committee Board for Health Research and Development Center, Nakhon Ratchasima Public Health Provincial Office (KHE 2022/36, May 30, 2022) and Buriram Provincial Health Office (BRO 2022/015, July 11, 2022,) approved this study. All participants meeting the inclusion criteria were given the information about the study. The participants aged ≥19 years signed informed consent forms before collecting data. For participants under 19 years, consent was provided by parents/guardians in addition to participants. No hazards or risks were associated with participation in the study. The principal investigator (PI) and co-principal investigator (co-PI) carefully monitored the participants' conditions for any changes during the program. If any complications were found, such as severe preeclampsia, preterm labor, or heavy vaginal bleeding, the participants were referred to secondary and tertiary care physicians in compliance with the guidelines for systematic treatment and services.

Research Instruments: Six questionnaires were used to collect data:

The Socio-demographic Information Form encompassed variables such as age, gravida status, gestational age at the commencement of the study, pregnancy planning, marital status, married cohabitation, level of education, occupation, monthly income, body mass index, history of abortion, preterm labor history, pregnancy-related complications, and family caregiver.

The Knowledge of Preterm Labor Prevention Questionnaire, developed by the PI through a literature review, consists of 20 items categorized into terminology clarification (1 item), causes and risk factors (7 items), effects (3 items), symptoms (3 items), and prevention/self-care (6 items). Respondents provide binary "yes = 1" or "no = 0" responses to each item, yielding scores ranging from 0 to 20. One example: "Do individuals with a history of preterm birth in previous pregnancies have an increased likelihood of experiencing preterm delivery in their current pregnancy?" A higher score indicates higher knowledge. Five experts, three faculty members in maternity-newborn nursing, one obstetrician, and one professional nurse in the maternity-newborn ward reviewed the content for validity. The responses were binary, categorized as either correct or incorrect. The instrument exhibited a CVI of .90, and the internal consistency reliability was assessed in a pilot sample of 30 participants who met the same inclusion criteria as those in the main study, resulting in Kuder-Richardson 20 (KR-20) alpha coefficients of .71 for the pilot sample and .70 for the main study.

The Attitude about Preterm Labor Prevention Questionnaire: This was developed by the PI following a literature review and encompasses 20 items organized into two dimensions: attitude about preventing preterm labor positively, "Scheduled antenatal care giving knowledge to prevent premature birth." and negatively, "A premature birth is like a normal birth." Participants were instructed to evaluate each item using a 5-point Likert scale, with ratings ranging from 1 to 5. Here, a score of 1 indicated "I strongly disagree," while a score of 5 denoted "I strongly agree". The score ranges from 20 to 100, with higher scores indicating a more favorable attitude towards self-care. The same five experts validated the instrument for content validity, which yielded a CVI of .88. The assessment of internal consistency reliability was conducted on a group of 30 participants who met the identical inclusion criteria as those involved in the main study. Cronbach's alpha coefficient values for the pilot and main study were .84 and .75, respectively, which is considered acceptable.

The Preventive Preterm Behavior Labor Questionnaire was modified with permission from the Preterm Labor Prevention Behavior Assessment developed by Petchararak.[26] It consists of 29 items with two dimensions: activities for preventing the risk of preterm labor positively, "You assess abdominal distention or abdominal pain by yourself," and negatively, "You work more than 8 hours each day." Participants were assigned to assess each item using a 4-point Likert scale from 1 (never) to 4 (regularly), resulting in potential scores ranging from 29 to 116.

A higher score denotes a higher level of proficiency in self-care practices. Following this, the instrument underwent rigorous content validity assessment by the same five experts. It yielded a CVI of .99. Internal consistency reliability was tested in 30 participants who met the same inclusion criteria as the participants in the main study. Cronbach's alpha coefficients were .73 and .70 for the pilot and main studies, respectively.

The Outcome of Pregnancy Questionnaire, includes gestational age at delivery and preterm labor during pregnancy, based on hospital records.

The Preterm Labor Risk Assessment Form was developed by Chawanpaiboon.[34] The PI received authorization for its use from the author and the Department of Obstetrics and Gynecology within the Faculty of Medicine Siriraj Hospital, Mahidol University, Thailand.

The Preterm Labor Prevention Program (PLPP)

The PLPP was developed based on the HBM,[29] which included perceived susceptibility, perceived seriousness, perceived benefits, perceived barriers to action and cues to action.[35] This program design included activities promoting perception, awareness, knowledge, attitude and practice. Additional focus was on support from surrounding people such as 1) family members (parents, husband, and siblings) who participate in the care of pregnant women to prevent preterm labor and preterm birth; and 2) health care providers (PI and co-PI) who served to educate on the prevention of preterm labor through group activities, individual counseling, online educational media, online counseling, and regular follow-up assessment until the gestational age reached full-term. Periodic assessment of behavior change corresponded with the Stage of Change Model.[38] This model, conceived by Prochaska and DiClemente in the late 1970s, centers around individual decision-making and asserts that behavioral changes, especially in habitual behaviors, do not happen quickly or decisively but evolve continuously through a cyclical process. Behavior modification typically requires approximately 3 to 6 months for noticeable change. Therefore, the duration of this program was extended over eight weeks, supplemented by a follow-up assessment four weeks post-program completion. Furthermore, this program assessed knowledge, attitude, and practice behaviors.

The program and activities are described in **Appendix, Table 1.** The PLPP aims to promote awareness regarding the risks associated with preterm birth, fostering knowledge and understanding and ultimately enhancing self-care capacity through a series of targeted activities.

The same group of five experts validated the content of the instruments for data collection and reviewed the congruence between the program concepts and activities. Then, the PI made revisions as recommended and tested the program in a trial group of 4-6 pregnant women under the care of the antenatal care clinic before implementation in the main study.

Routine Care: The participants received regular antenatal health care, which involved monitoring vital signs, general assessment of health, health education and medication to prevent preterm labor according to the clinical guidelines. Participants attended antenatal clinic appointments monthly until reaching a gestational age of 28 weeks. Subsequently, the appointment frequency changed to every two weeks from 28 to 36 weeks of gestational age, and finally, to weekly appointments from 36 weeks until labor and delivery. Furthermore, the participants underwent a second-trimester ultrasound examination and consistently attended maternal classes spanning the first through third trimesters of pregnancy.

Data Collection: We collected data from August 2022 to February 2023, once IRB approval had been granted. Participants who met the criteria underwent screening by healthcare professionals within the antenatal care unit. Subsequently, their voluntariness to participate in the study was assessed. Following this initial screening and voluntariness assessment, the participants were assigned randomly to either the experimental or control group. The study used a single-blind technique where neither the participants nor staff were informed about the group allocations. In this study, the experimental

group received the 8-week PLPP with routine care, while the control group exclusively received routine care provided by the antenatal clinics. The questionnaires assessed the effectiveness of both groups at three distinct time points: at baseline before the intervention), immediately and four weeks after program completion. These assessments were conducted using an online application. Preterm labor and preterm birth data were retrieved from hospital labor room records after childbirth.

Data Analysis: Data analysis was conducted using the Statistical Package for the Social Sciences (SPSS), Version 26.0, with descriptive statistics to illustrate the socio-demographic characteristics and demographics of the pregnant women. Independent sample t-tests, chi-square statistical analyses, and Fisher's Exact test were employed to compare the variances between the two groups at baseline. Subsequently, this study utilized a one-way repeated measures ANOVA to analyze the variances in total scores for knowledge, attitude and practice between groups, opting to use repeated measures ANOVA for testing the variances within groups among points of measurement. In addition, this study used a chi-square test to examine the variances in preterm labor and preterm birth rates between groups.

Results

Characteristics of the Pregnant Women

As indicated in **Table 1**, most pregnant women in both groups fell within the age range of 15-49 years. On their first visit to the antenatal clinics, the mean gestational ages were 21.81 weeks and 22.32 weeks in the experimental and control groups, respectively. No significant differences between the groups were found at baseline regarding socio-demographics and other characteristics.

Table 1. Socio-demographic characteristics of the participants and family caregivers

Socio-demographic characteristics	Experimental group (n = 32)	Control group (n = 34)	Statistical value	p-value
Age (years)			-0.93	0.358[a]
Mean (SD)	25.44 (6.99)	26.94 (6.19)		
Range	15-38	16-45		
Gestational age at first visit in the program			-1.13	0.261[a]
Mean (SD)	21.81(1.80)	22.32 (1.85)		
Range (wks)	20-24	20-24		
Income (Baht)			-0.96	0.339[a]
Mean	12,894.38	15,852.94		
(SD)	(7023.62)	(15,987.46)		
Range	(3,000-35,000)	(3,000-100,000)		
Body mass index (kg/m^2)			-0.73	0.469[a]
Mean (SD)	23.18 (4.48)	24.07 (5.81)		
Range	(16.63-36.00)	(15.43-36.13)		
Gravidarum			0.36	0.060[c]
First gravidarum	17 (53.13)	9 (26.47)		
Second gravidarum	10 (31.25)	9 (26.47)		
Third gravidarum	4 (12.5)	11(32.35)		
Fourth gravidarum	1(3.12)	4 (11.76)		
More than fourth	0	1 (2.94)		
Abortion History			0.12	0.447[c]
Yes	3	6		
No	29	28		

Table 1. Socio-demographic characteristics of the participants and family caregivers (Cont.)

Socio-demographic characteristics	Experimental group (n = 32)	Control group (n = 34)	Statistical value	p-value
Preterm labor history			0.10	0.469[c]
Yes	5	3		
No	27	31		
Pregnancy planning			1.78	0.183[b]
Planned	9	5		
Unplanned pregnancy	23	29		
Marital status			0.34	0.056[c]
Married and living with spouse	24 (75.00)	28 (82.35)		
Married, but not living with spouse	1 (3.13)	3 (8.82)		
Not married, but living with spouse	7 (21.87)	1(2.94)		
Single	0	1 (2.94)		
Divorce	0	1 (2.94)		
Employment status			0.36	0.137[c]
Housewife	15 (46.88)	24 (70.59)		
Farmer	1 (3.13)	0		
General contractor	7 (21.87)	1 (2.94)		
Shopkeeper	2 (6.25)	2 (5.88)		
Government service	4 (12.50)	4 (11.77)		
Company worker	3 (9.37)	2 (5.88)		
Student	0	1 (2.94)		
Educational attainment			0.09	0.975[c]
Grade 6 or less	2 (6.25)	2 (5.88)		
Secondary school	14 (43.75)	14 (41.18)		
High school graduate	8 (25.00)	10 (29.41)		
Vocational certificate	1 (3.12)	2 (5.88)		
Bachelor's degree	7 (21.87)	6 (17.65)		
Complications during pregnancy			0.10	0.951[c]
No	24 (75.00)	25 (73.53)		
Yes				
Diabetes mellitus	3 (9.38)	2 (5.88)		
Hypertension	1 (3.12)	1 (2.94)		
Hyperemesis	1 (3.12)	1 (2.94)		
Other	3 (9.38)	5 (14.71)		
Family caregiver			0.49	0.485[b]
Spouse	11 (34.40)	9 (26.50)		
Parents or relatives	21 (65.60)	25 (73.50)		

Note. [a] = independent t-test, [b] = chi-square, [c] = Fisher's Exact Test

Preterm Labor Prevention Program (PLPP) Effectiveness

As shown in **Table 2**, there were no significant differences between the groups' baseline scores for knowledge, attitudes, and self-care practices. However, immediately and four weeks after completing the 8-week program, these scores were significantly higher in the intervention group compared to the control group. Furthermore, there were noteworthy alterations in knowledge, attitudes, and self-care practices over time, and the interaction between time and group was statistically significant, as outlined in **Table 3.** Multiple pairwise comparisons employing the Bonferroni test were conducted between each measurement point, revealing significant increases in knowledge, attitudes, and self-care practice scores for the experimental group from baseline to the immediate program and from baseline to 4 weeks after program completion. Conversely, within the control group, no statistically significant difference was observed in the attitude scores across the three times of measurements. Still, knowledge increased significantly from baseline to the immediate program end and from baseline to 4 weeks after completion. In contrast, practice scores increased significantly only from immediately to 4 weeks after the program completion **(Table 4).**

Table 2. Comparison of the mean knowledge, attitude and practice score before and after intervention at each time point.

Outcome variables	Experimental group (n = 32) M (SD)	Control group (n = 34) M (SD)	SE	p-value
Knowledge score				
Time 1	15.66 (2.97)	14.21(2.82)	0.71	.500
Time 2	16.81(2.31)	14.82 (2.79)	0.63	.003
Time 3	17.75 (1.46)	15.32 (2.42)	0.50	< .001
Attitude Score				
Time 1	85.03 (7.41)	85.00 (7.48)	1.83	.986
Time 2	94.31(4.28)	83.41(7.65)	1.54	< .001
Time 3	97.66 (1.56)	83.29 (8.28)	1.49	< .001
Practice Score				
Time 1	87.13 (6.81)	87.68 (8.58)	1.91	.774
Time 2	101.44 (7.03)	91.47 (9.27)	2.04	< .001
Time 3	110.56 (3.72)	94.38 (7.25)	1.43	< .001

Note. T1 = Baseline (pre-intervention), T2 = Week 8 (immediately after completion), T3 = Week 12 (4 weeks after program completion)

Table 3. One-way repeated measures ANOVA of knowledge scores, attitude scores and practice scores

Source of variation	Type III sum of squares	df	Mean square	F	p-value
Knowledge					
Within group					
time	85.316	1.413	60.393	29.310	< .001
Group*time	7.881	1.413	5.579	2.708	.090
Error	186.290	90.411	2.060		
Between groups					
Group	189.069	1	189.069	11.751	.001
Error	1029.744	64	16.090		

Table 3. One-way repeated measures ANOVA of knowledge scores, attitude scores and practice scores (Cont.)

Source of variation	Type III sum of squares	df	Mean square	F	p-value
Attitude					
Within group	1037.542	1.646	630.382	21.192	< .001
Time	1843.562	1.646	1120.098	37.656	< .001
Group*time	3133.337	105.337	29.746		
Error					
Between groups					
Group	3515.627	1	3515.627	42.882	< .001
Error	5247.020	64	81.985		
Practice					
Within group					
Time	7590.486	2	3795.24	116.02	< .001
Group*time	2358.365	2	1179.18	36.05	< .001
Error	4187.201	128	32.71		
Between groups					
Group	3599.929	1	3599.93	37.11	< .001
Error	6207.990	64	97.000		

Table 4. Pairwise comparisons using Bonferroni of the mean difference in total scores between each pair of time differences in the intervention and control groups (n = 32, 34)

Variable	Time	Mean difference	Std. error	p-value
Knowledge scores	Experimental group			
	T1 vs T2	-14.31	1.51	< .001
	T1 vs T3	-23.44	1.48	< .001
	T2 vs T3	-9.13	1.28	< .001
	Control group			
	T1 vs T2	-3.79	1.47	.012
	T1 vs T3	-6.71	1.44	< .001
	T2 vs T3	-2.91	1.25	.023
Attitude skills	Experimental group			
	T1 vs T2	-9.28	1.33	< .001
	T1 vs T3	-12.63	1.41	< .001
	T2 vs T3	-3.34	0,91	.001
	Control group			
	T1 vs T2	1.59	1.29	.223
	T1 vs T3	1.71	1.38	.217
	T2 vs T3	0.12	0.89	.895
Practice	Experimental group			
	T1 vs T2	-1.16	0.32	.001
	T1 vs T3	-2.09	0.37	< .001
	T2 vs T3	-0.94	0.19	< .001
	Control group			
	T1 vs T2	-0.62	0.31	.051
	T1 vs T3	-1.12	0.36	.051
	T2 vs T3	-0.50	0.18	.008

Note. T1 = Baseline (pre-intervention), T2 = Week 8 (immediately after completion) , T3 = Week 12 (4 weeks after program completion)

No distinctions were detected between the experimental and control groups when comparing the preterm labor and birth rates (**Table 5**). However, if considering the incidence of preterm labor as a percentage, the rate of the control group was 20.60%, higher than the experimental group, which was only 6.25%. In addition, the preterm birth rate in the control group was 20.60%, while it was only 3.10% in the experimental group but without statistical significance.

Table 5. Comparison of the preterm labor rates and preterm birth rates between the experimental and control groups

Outcome variables	Experimental group (n = 32)	Control group (n = 34)	Chi-square	p-value
Preterm labor				
Yes	2 (6.25)	7 (20.60)	4.72	.055
No	30 (93.75)	27 (79.40)		
Preterm birth				
Yes	1 (3.10)	7 (20.60)	2.88	.151
No	31 (96.90)	27 (20.60)		

Discussion

This study indicated the effectiveness of the Preterm Labor Prevention Program (PLPP) for high-risk pregnant women in improving knowledge, attitudes, and self-care practice, as well as likely to decrease preterm labor and preterm birth rate. This is because the PLPP applied a theoretical framework of the HBM,[29] which intensively provided information on risks, seriousness, benefits of prevention behavior, barriers to action and cues to action, and providing caregiving guidelines through individual and group instruction. In addition, video clips emphasized how to care for themselves and answered questions at weeks 1, 4, and 8. Also, the program emphasizes knowledge acquisition through diverse methods, including group discussions, individual counseling, and the utilization of various online and multimedia resources for convenient information access and comprehension. Furthermore, the program reduced pregnant women's obstacles in dealing with various challenges independently.

Meanwhile, this program encouraged the active involvement of family members in caregiving provided continuous guidance and offered prompts for home-based practices to mitigate the risk of preterm birth. Moreover, the program enhances access to information on topics where pregnant women may require assistance in decision-making. It achieves this by introducing channels for seeking clarification and providing follow-up through phone calls and online communication to monitor and address issues promptly. In addition, the participants received 1-2 monthly phone or online follow-ups until delivery, particularly monitoring high-risk cases. Optional online/telephone counseling was offered, and family involvement was encouraged from the start to support pregnant women.

The findings of our study align with previous studies, which found a significant and positive correlation between the perceived risk of preterm labor and engagement in prevention self-care behaviors.[25-27] Also, previous studies found that continuing to assess the risk of preterm labor, symptom monitoring via telephone, and uterine contraction tracking significantly prevented preterm labor.[20-22] Despite their self-care knowledge, our study revealed that some women in the experimental group faced challenges due to demanding work involving prolonged standing and walking. A predictive model for pregnant adolescents showed that those in gardening and similar jobs had a higher risk of preterm labor than the unemployed.[39]

The results of this study supported all hypotheses, so the study confirms the validity of HBM[29] in that enhanced susceptibility, perceived seriousness, perceived

benefits, perceived barriers to action and cues to action can enhance self-care practice to prevent preterm labor in high-risk groups. However, this study did not measure the perception of susceptibility, seriousness, benefits, barriers and cues to action. Still, it measured primary outcomes as knowledge, attitudes, and self-care practice and the secondary outcomes as preterm labor and preterm birth rates. The acquisition of knowledge arises from realizing its importance, actively seeking information, and pursuing knowledge, which signifies a pronounced attitude indicating acceptance of its significance, readiness to put it into practice, and continuous application. This aligns with the learning theory[40] that encompasses the cognitive, affective, and psychomotor domains in behavior. Hence, this study emphasized knowledge, attitudes, and self-care practices.

Limitations

Our study has limitations; firstly, the PLPP might not be suitable for implementation in groups of pregnant women who do not have relatives, friends or close acquaintances to take care of them. Secondly, activities in the PLPP require a smartphone for watching video clips and completing questionnaires in Google form. Therefore, this program is only suitable for cases with communication tools. Thirdly, this program may not be suitable for pregnant women with significant health issues that increase the risk of preterm birth, including conditions like premature rupture of membranes, cervical cerclage, and placenta previa. Fourthly, this study was conducted in Northeastern Thailand. Thus, the findings may not be generalizable to other geographical regions.

Conclusions and Implications for Nursing Practice

The PLPP is effective for high-risk pregnant women in improving knowledge, attitudes, and self-care practice and is likely to decrease preterm labor and preterm birth. Nurses and midwives can use this program to assess these pregnant women's high-risk group and provide antenatal care through PLPP as early as possible. Nevertheless, special upskilling for the antenatal care of high-risk cases is needed, and further testing of the program and its effectiveness is required on a larger scale with more participants in different settings.

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Appendix

Table 1: Program and activities for participants and family members

Week/ Time schedule	Objective	Activities
Week 1 Preparation and the first session, 45-60 minutes	- To introduce the intervention - To foster awareness, knowledge, and positive attitudes toward preterm labor prevention - To increase perception of susceptibility and seriousness of preterm labor - To understand the barriers and benefits of self-care practice on preterm labor - To involve family to participate and reduce the barriers	- Participants and their family members were introduced to the intervention. **Activity 1: "Necessary Knowledge to Reduce Risks"** - Both group and individual health education sessions are provided, which include access to manuals, handbooks, and video clips delivered online. - Contents included preterm labor conditions, susceptibility to preterm labor, seriousness of preterm labor, benefit of preterm labor prevention and self-care during pregnancy. **Activity 2: "Depending on the Family"** - Encourage families to participate in the care of pregnant women by providing knowledge, giving advice and participating in the assessment of the behavior of pregnant women in the manuals
Week 4 The second session, 45-60 minutes	- To reduce the barriers to accessing services - To recognize and take appropriate self-care practice to alleviate preterm labor	**Activity 3: "What Should I Do with Pain Like This?"** - Watching simulations video clips with content on the problem, causes, treatment and self-care actions when labor is premature - Consultation with the PI via online and phone for premature labor problems
Week 8 The third session, 45-60 minutes	- To understand self-care practice when there is a suspicion of preterm labor - To reduce barriers to accessing services	**Activity 4: "If You Want to Know, We Have to Provide"** - Group and individual activities for asking and answering about the problems of preterm labor; online/ phone consultation - Increasing problem-solving skills of premature labor by watching a video clip on asking and answering about preterm labor through online channels - Online counseling until delivery

ประสิทธิผลของโปรแกรมการป้องกันภาวะเจ็บครรภ์คลอดก่อนกำหนดของสตรีตั้งครรภ์ที่มีภาวะเสี่ยงสูง: การวิจัยเชิงทดลองแบบสุ่มชนิดมีกลุ่มควบคุม

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บทคัดย่อ: ภาวะเจ็บครรภ์คลอดก่อนกำหนดเป็นสาเหตุสำคัญที่ทำให้เกิดการคลอดก่อนกำหนด ซึ่งมีผลกระทบต่อพัฒนาการและภาวะสุขภาพของทารก การวิจัยเชิงทดลองแบบสุ่มชนิดมีกลุ่มควบคุมนี้มีวัตถุประสงค์ เพื่อศึกษาประสิทธิผลของโปรแกรมป้องกันภาวะเจ็บครรภ์คลอดก่อนกำหนดของสตรีตั้งครรภ์ที่มีภาวะเสี่ยงต่อภาวะเจ็บครรภ์คลอดก่อนกำหนด โดยมีผลลัพธ์ระยะสั้น คือ ความรู้ เจตคติ และการปฏิบัติตนเพื่อป้องกันภาวะเจ็บครรภ์คลอดก่อนกำหนด และผลลัพธ์ระยะยาว คือ อัตราการเกิดภาวะเจ็บครรภ์คลอดก่อนกำหนด และอัตราการคลอดก่อนกำหนด กลุ่มตัวอย่าง คือ สตรีตั้งครรภ์ที่มีความเสี่ยงต่อภาวะเจ็บครรภ์คลอดก่อนกำหนด กลุ่มตัวอย่างเป็นผู้มีความเสี่ยงต่อภาวะเจ็บครรภ์คลอดก่อนกำหนด อายุ 15-49 ปีจำนวน 66 คน ฝากครรภ์ที่คลินิกฝากครรภ์ของโรงพยาบาลทั่วไปใน 2 จังหวัดในภาคตะวันออกเฉียงเหนือของประเทศไทย โดยมีการสุ่มตัวอย่างเข้ากลุ่มทดลองจำนวน 32 คน และกลุ่มควบคุม 34 คน ทั้งนี้กลุ่มทดลองรับการดูแลจากโปรแกรมป้องกันภาวะเจ็บครรภ์คลอดก่อนกำหนดและการดูแลตามปกติของแผนกฝากครรภ์ ส่วนกลุ่มควบคุมรับการดูแลจากคลินิกฝากครรภ์เท่านั้น แบบสอบถามประเมินผลลัพธ์ระยะสั้น ได้แก่ ความรู้ ทัศนคติ และการปฏิบัติตน เพื่อป้องกันภาวะเจ็บครรภ์คลอดก่อนกำหนด ส่วนผลลัพธ์สุดท้าย ได้แก่ การเกิดภาวะเจ็บครรภ์คลอดก่อนกำหนด และอัตราการคลอดก่อนกำหนด วิเคราะห์ข้อมูลด้วยสถิติการวิเคราะห์ความแปรปรวนทางเดียวแบบวัดซ้ำ และสถิติไคสแควร์ เพื่อทดสอบความแตกต่างของอัตราการเกิดภาวะเจ็บครรภ์คลอดก่อนกำหนด และอัตราการคลอดก่อนกำหนดระหว่างกลุ่ม

ผลการวิจัยเมื่อเวลาสิ้นสุดโปรแกรม และ 4 สัปดาห์หลังสิ้นสุดโปรแกรม พบว่า คะแนนเฉลี่ยความรู้ เจตคติ และการปฏิบัติของกลุ่มทดลองสูงกว่าก่อนการเข้าร่วมโปรแกรม และสูงกว่ากลุ่มควบคุมอย่างมีนัยสำคัญ ด้านอัตราการเกิดภาวะเจ็บครรภ์คลอดก่อนกำหนด และอัตราการคลอดก่อนกำหนด แม้ว่าจะไม่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติระหว่างกลุ่มทดลอง และกลุ่มควบคุม แต่พบว่ากลุ่มควบคุมมีอัตราการเจ็บคลอดก่อนกำหนด และอัตราการคลอดก่อนกำหนดสูงกว่ากลุ่มทดลอง ดังนั้นพยาบาลและผดุงครรภ์สามารถใช้โปรแกรมนี้เพื่อเพิ่มพูนความรู้ ทัศนคติ และการปฏิบัติตน เพื่อป้องกันภาวะเจ็บครรภ์คลอดก่อนกำหนดเพื่อป้องกันภาวะเจ็บครรภ์คลอดก่อนกำหนด และการคลอดก่อนกำหนด อย่างไรก็ตามจำเป็นต้องมีการศึกษาเพิ่มเติมกับกลุ่มตัวอย่างมากขึ้น

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คำสำคัญ: ภาวะเสี่ยงสูง สตรีตั้งครรภ์ การคลอดก่อนกำหนด ภาวะเจ็บครรภ์คลอดก่อนกำหนด การป้องกัน การวิจัยเชิงทดลองแบบสุ่มชนิดมีกลุ่มควบคุม

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