

STUDY PROTOCOL

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Prenatal labor analgesia education program on outcomes for primiparas: study protocol for a randomized controlled trial

Jiali Wu¹, Jing Chen¹, Weiwen Zhang², Jiangtao OuYang¹, Jia Li¹ and Xujuan Zheng^{3*}

Abstract

Background A significant number of primiparous women lack awareness of labor epidural analgesia, resulting in lower acceptance of labor epidural analgesia. Additional prenatal education may help primiparas understand labor epidural analgesia and increase labor epidural analgesia rates. This randomized controlled trial (RCT) will evaluate the effects of an online and offline prenatal labor epidural analgesia education program for primiparas to improve their labor epidural analgesia rate and to reduce their misunderstanding of labor epidural analgesia and fear of birth.

Methods A single-blinded, randomized, controlled, parallel-design trial will be conducted. Based on the Theory of Planned Behavior, online and offline prenatal labor epidural analgesia education program has five modules: (a) elementary knowledge, (b) attitude, (c) subjective norm, (d) perceived behavioral control and (e) behavioral intention. Primiparous women will be recruited in the obstetrics department or midwife clinic of a tertiary hospital in Shenzhen, China. The participants ($N=196$) will be randomly allocated to the intervention group ($N=98$) that receives routine prenatal education and access to the online and offline prenatal labor epidural analgesia education program and the control group ($N=98$) that receives routine prenatal education. Labor epidural analgesia rate will be extracted from the electronic medical record; misunderstanding and intention of labor epidural analgesia and fear of birth will be measured at baseline and immediately after the intervention. The study was ethically approved in November 2023.

Discussion If the online and offline prenatal labor epidural analgesia education program has positive outcomes, it may offer an effective intervention program to decrease misperceptions of labor epidural analgesia and fear of birth and to improve the labor epidural analgesia rate for Chinese primiparas. As the first RCT study to evaluate the effect of the online and offline prenatal labor epidural analgesia education program with a strict research design and a theoretical framework, this research will provide evidence on prenatal labor analgesia health education for clinical practice in China.

Trial Registration Registered at the Chinese Clinical Trials.gov on January 11th, 2024. Trial Registration Number: ChiCTR2400079767.

Keywords Labor epidural analgesia, Primiparas, Study protocol, Prenatal education program, Health education

*Correspondence:

Xujuan Zheng
zhengxujuan@szu.edu.cn

¹Department of Graduate and Scientific Research, Zhuhai Campus of
Zunyi Medical University, Zhuhai, China

²Department of Obstetrics, Shenzhen University General Hospital,
Shenzhen, China

³School of Nursing, Medical School, Shenzhen University, Shenzhen,
China



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Background

Childbirth pain is a complex phenomenon and one of the most painful experiences of a woman's life [1]. Many pregnant women had great worry about the severity of childbirth pain. Thus, they sought ways to relieve the pain; even in some instances [2], elective cesarean section was requested due to fear of delivery [3]. Association of Anaesthetists of Great Britain and Ireland suggested that all pregnant women should be offered information on analgesia [4]. Labor epidural analgesia (LEA) is considered the most effective way to relieve pain and is recommended by the World Health Organization [5]. However, LEA is more commonly used in Western countries. LEA rates of 75% have been reported in France and 77.1% in Belgium, similar to the 80% rate in the United States [6, 7]. It was reported that 36% of the Chinese people still did not know about LEA, and the overall prevalence rate of LEA in China is only 30% [8]. This stands in stark contrast to Western countries. The maternal choice of LEA depends on the level of education, culture, financial status, and fear of complications for mothers [9]. It is likewise influenced by the environment in which they receive prenatal and delivery care, the type of care they receive, and the care providers [10]. Most women acquire LEA knowledge mainly through the Internet or friends rather than health professionals [3, 11].

Several studies indicate the need for effective and accurate targeted interventions [12–14]. Health education can improve maternal knowledge of LEA [15, 16]; it is vital to predict the willingness of primiparous women to request LEA [11]. Conventional interventions, including face-to-face education and distributing pamphlets, have been identified to be associated with improving maternal knowledge and willingness to LEA but have yet to increase their LEA rate [17, 18]. These traditional interventions have some limitations: Firstly, the feasibility and generalizability of traditional interventions were challenged by the large numbers of pregnant women and the shortage of health care providers. Secondly, time constraints are an essential barrier to pregnant women's participation in face-to-face interventions. Thirdly, traditional interventions often fail to cover every family member, which does not allow for adequate discussion between the mother and her family.

With the development of network technology, most researchers prefer the Internet-based intervention mode. For instance, a study in Taiwan assessed the outcomes of a web-based video educational intervention on maternal satisfaction and the level of comprehension in LEA. The intervention group received a leaflet with a Quick Response (QR) code during the 28th week of pregnancy, allowing parturients to watch health education videos on their smartphones. In contrast, the control group received explanations in the delivery room

upon admission for childbirth. The results indicated that the intervention group demonstrated higher scores on satisfaction with the information received about LEA (Mean Difference = 0.21, 95%CI = 0.04–0.38, $P = 0.007$) and understanding of the side effects of the LEA, such as headaches (Mean Difference = 0.22, 95%CI = 0.01–0.43, $P = 0.022$) [19]. However, one-size-fits-all internet-based interventions may be less suitable for people with limited health literacy [20, 21], which also means that online interventions are challenging to customize for personalized measures. In addition, internet-based interventions have significant shortcomings in low engagement and response rates due to less interaction and motivation [22]. Thus, a mixed intervention method is the best form in the present study, as it has the advantages of convenience and flexibility but also provides primiparous women with confidence in face-to-face support [23]. Previous studies have demonstrated that mixed intervention positively improved the willingness of LEA and knowledge [9, 15]. However, the latter study noted that most women in labor do not have access to educational programs due to the urgency of childbirth. LEA education is best implemented during prenatal care [15]. Meanwhile, Munro et al. also indicated that women prefer to receive information about LEA during the prenatal period rather than during childbirth [18]. Therefore, a prenatal, online, and offline LEA intervention needs to be designed. To our knowledge, similar randomized controlled trials (RCTs) have not been conducted in mainland China.

Evidence suggests that the number of deliveries predicts women's knowledge of labor analgesia [24]. Primipara women have less LEA knowledge than multipara women, owing to their lack of previous delivery experience [25], so they are an essential group in LEA education. In addition, as the wife's most important supporter, the husband participating in prenatal education together is a necessary part of LEA education. Evidence suggests that the participation of both spouses in health education is conducive to improving health behaviors during pregnancy and promoting harmony in the couple's relationship [26, 27]. So, couples in LEA educational programs are a crucial part of it. Previous studies have confirmed the need for educational programs on LEA for pregnant women. However, there are few prenatal LEA educations for primiparas that include spouses. Therefore, an online and offline prenatal epidural labor analgesia education program (PAP) for Chinese primiparous women and their spouses will be conducted to improve their LEA rate and to reduce their misunderstanding of LEA and fear of birth.

Methods

Aim

This study aims to evaluate the effects of PAP on Chinese primiparous women to increase the rate of LEA, reducing primiparas' misunderstanding and fear of birth.

Hypotheses

This study hypothesizes that compared with the control group at the end of the study, primiparas in the intervention group will report statistically significant:

- 1) Increased the use of LEA;
- 2) Reduced misunderstanding of LEA;
- 3) Reduced the fear of prenatal delivery.

Trial design

A single-blinded, randomized, controlled, parallel design will be conducted to assess the effect of PAP on Chinese primiparous women in the third trimester. The study follows the SPIRIT 2013 Statement and the Standard Protocol of Clinical Trials guidelines [28]. The schematic diagram of recruitment, intervention, and evaluation is shown in Fig. 1.

Study setting and participants

The research will be carried out in a tertiary hospital in China. The inclusion criteria will be: (1) single pregnancy primipara confirmed by ultrasound; (2) aged 18 years

or above; (3) no complications of pregnancy or other organic diseases, e.g., heart disease, chronic kidney disease, serious cardio-cerebrovascular, digestive, or hepatic function disorders. (4) have the ability to understand and be proficient in Mandarin and Chinese characters. (5) ability to use a WeChat public account and WeChat group. (6) willing to participate in this study. The exclusion criteria will be (1) with contraindications to epidural anesthesia (e.g., coagulopathy); (2) with severe mental or physical diseases (e.g., major depressive disorder or severe hypertension); (3) attending other painless childbirth education programs at the same time; Dropout criteria: (1) participants withdrew from the study due to various reasons; (2) through medical diagnosis must be cesarean section; (3) delivered before 37 weeks of gestation. In addition, the inclusion criteria for spouses were the same as those for primiparas in Criteria 2, 3, 4, 5, and 6, and their exclusion criteria were identical to Criteria 2 and 3 for primiparas.

Recruitment

Participants will be recruited when pregnant women attend a tertiary hospital's obstetrics clinic or midwife clinic. Since recruitment is one-on-one at the clinic, this greatly avoids intergroup contamination. The obstetric nurses will orally introduce the purpose and content of this study to women who meet the inclusion criteria. The researchers will approach women who verbally agree

	Recruitment			Interventions		Assessments		
	Eligibility screen	Informed consent	Allocation	PAP+routine care	Routine care	Pre-test	Post-test	After childbirth
Time	Before 28 weeks of gestation			Between 29 and 36 weeks of gestation		Before 28 weeks of gestation	36 weeks of gestation	After childbirth
Eligibility screen	X							
Informed consent		X						
Demographic data						X		
W-DEQ-A-SC						X	X	
TPBT						X	X	
Epidural questionnaire						X	X	
Allocation			X					
Intervention				X	X			
Rate of LEA								X

Fig. 1 The schematic diagram of recruitment, intervention, and evaluation. Abbreviations: W-DEQ-A-SC: Simplified Chinese version of the Wijma Delivery Expectancy Questionnaire; TPBT: Self-rating scale of painless delivery intention based on the theory of planned behavior; LEA: Labor epidural analgesia; PAP: Online and Offline Prenatal Epidural Labor Analgesia Education Program

to participate by providing them with written informed consent and answering any questions about the research. In this approach, primiparas will not be asked to make on-the-spot decisions to ensure they have enough time to read the informed consent and discuss it with their family members. The researchers will acquire participants' written informed consent when they initiate contact. Data will be collected before randomization (baseline) and immediately after the intervention. Recruitment of participants began in January 2024.

Sample size

The sample size will be calculated based on previous research [15]. The study found that the LEA rate was 80% in the intervention group and 60% in the control group. We use the following formula:

$$N = \frac{[Z_{\alpha} \sqrt{2P(1-P)} + Z_{\beta} \sqrt{P_c(1-P_c) + P_e(1-P_e)}]^2}{(P_c - P_e)^2}$$

($\alpha = 0.05$, $\beta = 0.20$; $Z_{\alpha} = 1.96$, $Z_{\beta} = 0.84$; $P_c = 0.80$, $P_e = 0.60$, $P = (P_c + P_e)/2$)

Each group will be 81 primiparous women. Assuming an attrition rate of about 20%, 196 women (98 in each group) are required.

Randomization and blinding

A computerized random number generator will be used to randomly assign participants into the intervention group and the control group with a distribution ratio of 1:1. The allocation sequence will be put into opaque and sealed envelopes by investigators not directly associated with this project to ensure that the randomization assignment is not leaked in advance. Blinding will not be possible for the researchers during the research process; however, the group allocation will be masked to participants and outcome assessors. Additionally, to avoid implementation bias during childbirth, anesthesiologists, labor nurses, and obstetricians will be blinded to group assignments. Unblinding will occur after the intervention is complete.

Intervention

Primiparas assigned to the control group will receive routine education at the hospital's antenatal clinic. Routine education includes (1) access to labor pain pamphlets (2) posters and bulletin boards for the obstetrics department outpatient clinic. Primiparas assigned to the intervention group will receive PAP in addition to the above routine health education. When the researcher distributes brochures to primiparous women in the control group, they will briefly explain the main content (approximately 3–5 min). Pregnant women will then be guided to view the bulletin boards at their discretion.

The theoretical framework of PAP was based on the Theory of Planned Behavior (TPB), which was developed by American psychologist Ajzen [29]. The theory describes how behavioral intentions influence people's actual behavior. It consists of five elements: attitude, subjective norm, perceived behavioral control, and behavioral intentions and behaviors [30]. The theory is well-developed and can guide intervention models, predict individual behavioral attitudes and changes, and intervene promptly to improve personal attitudes toward things and thus promote the implementation of behavior. It has been successfully applied to intervention studies of other diseases [31, 32]. In this study, behavioral attitudes refer to the positive or negative evaluations of women's attitudes toward painless delivery; subjective norms refer to the pressure women feel from their family and friends, especially their spouses, to support or oppose their decision to give birth; perceived behavioral control refers to the level of obstacles women perceive they will face if they choose to give birth without pain and the level of self-confidence in their behaviors; and behavioral intention refers to the final decision of women for epidural labor analgesia. LEA-related knowledge may affect women's awareness of LEA as an available choice in the future [33]. Therefore, PAP used the extended TPB theory (ETPB) [34] to guide the implementation of the intervention. The theoretical framework of the PAP is shown in Fig. 2.

Video presentations are one of the most commonly used forms of health education in labor analgesia. Video is more vivid and specific than verbal explanations or pictures, freeing health professionals from time-consuming, repetitive explanations [19, 35]. We will also incorporate other formats, such as pictures, text, etc. According to the situation in China, we use WeChat, a popular social software, as an online education platform, combining face-to-face classes and one-on-one interviews for intervention. The first phase of PAP reflects basic knowledge and attitudes and begins at 29–32 weeks of gestations. The details of the intervention are described in Table 1.

PAP (Fig. 3) lasts approximately eight weeks and is divided into 3 phases. Phase 1 is learning about knowledge and misconceptions of LEA, as shown by WeChat. The contents include (1) Definition, procedure, contraindications and indications, advantages, and side effects of LEA; (2) Common misconceptions about LEA, such as postpartum back pain, nerve damage, breastfeeding, and baby's intelligence (these misconceptions were summarized from three sources: collected from the online, previously published literature and in-person interviews); (3) Advantages and processes of natural childbirth; mechanisms and adverse effects of labor pain, and various methods of pain relief. Pregnant women can read/watch the texts/videos freely and repeatedly and can

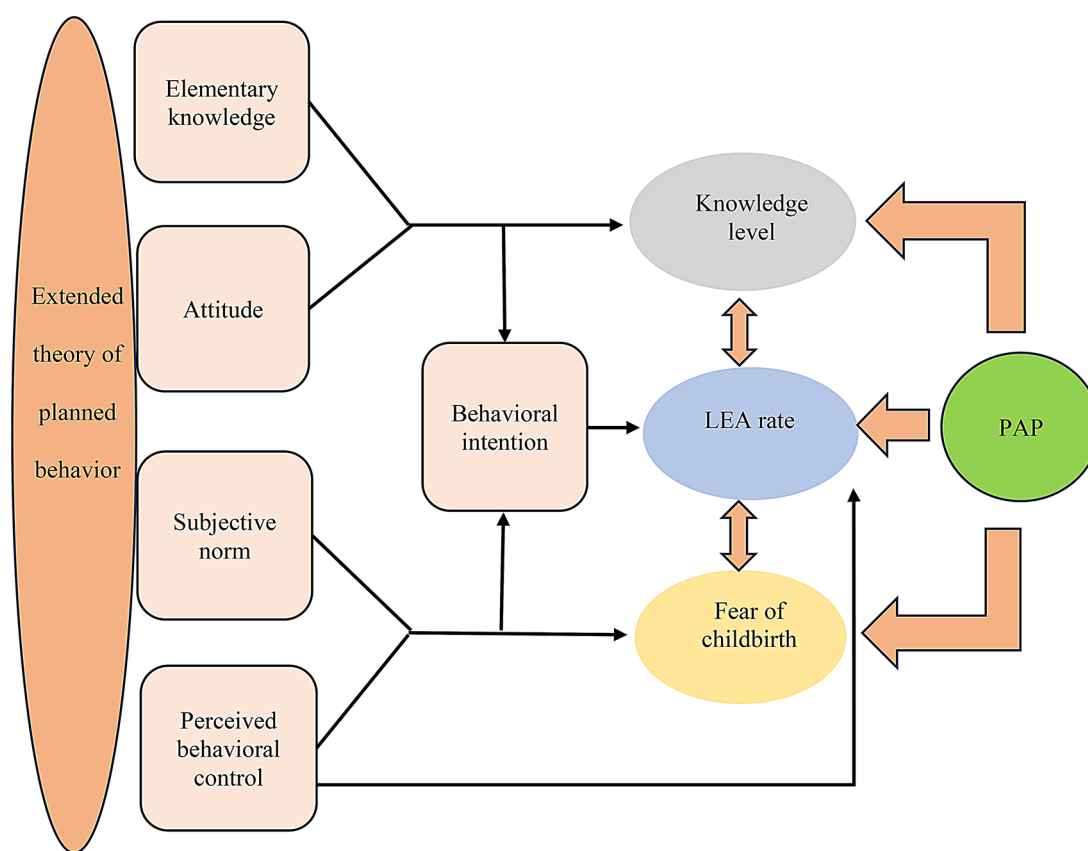


Fig. 2 The theoretical framework of the PAP. Note: The theoretical framework of the PAP was adapted from XueCheng [34]

discuss medical decisions with their family members. To increase compliance with this phase of the intervention, we will take the following measures: First, participants will receive weekly reminders during the first phase via phone or WeChat (a total of four reminders). Second, through the management interface of the WeChat Official Account Mini Program, researchers can monitor the number of visitors. If the number of visits within a given week is insufficient, additional reminders will be sent as needed.

The second phase of PAP reflects subjective norms and perceptual behavioral control and begins at 33–34 weeks of pregnancy. The theme of the second phase is to feel supported by others and overcome difficulties. The contents include (1) We will invite the partner to experience labor pains and then encourage him to express his feelings. The aim is to enhance the women's perception of the support of significant others; (2) Invite women who have experienced LEA to share their feelings. (Inclusion criteria were: natural delivery of a baby; successful use of LEA and having a favorable impression of it); (3) Use PowerPoint and video to explain the preparation process and precautions of LEA, including the appointment process, the preparation of materials, coordination of body position, relaxation training. The purpose is to increase

the proficiency of maternal cooperation, improve maternal tension and fear, and enhance courage and confidence. At this stage, we will carry out offline courses in batches according to when the pregnant women come to the hospital for prenatal examination. It is expected that there will be about 5–10 pregnant women in each batch.

The behavioral intention is reflected in the third phase of PAP. We will conduct one-to-one counseling at 35–36 weeks of pregnancy for both pregnant women and spouses. We will give counseling tailored according to their education level and cultural background, summarise and solve confusions and unresolved individualized difficulties encountered by the pregnant woman and her partner in the above interventions, and encourage them to express their thoughts and feelings at this stage.

Outcome measurement

Primary outcome

LEA rate: epidural usage will be extracted from the electronic medical record.

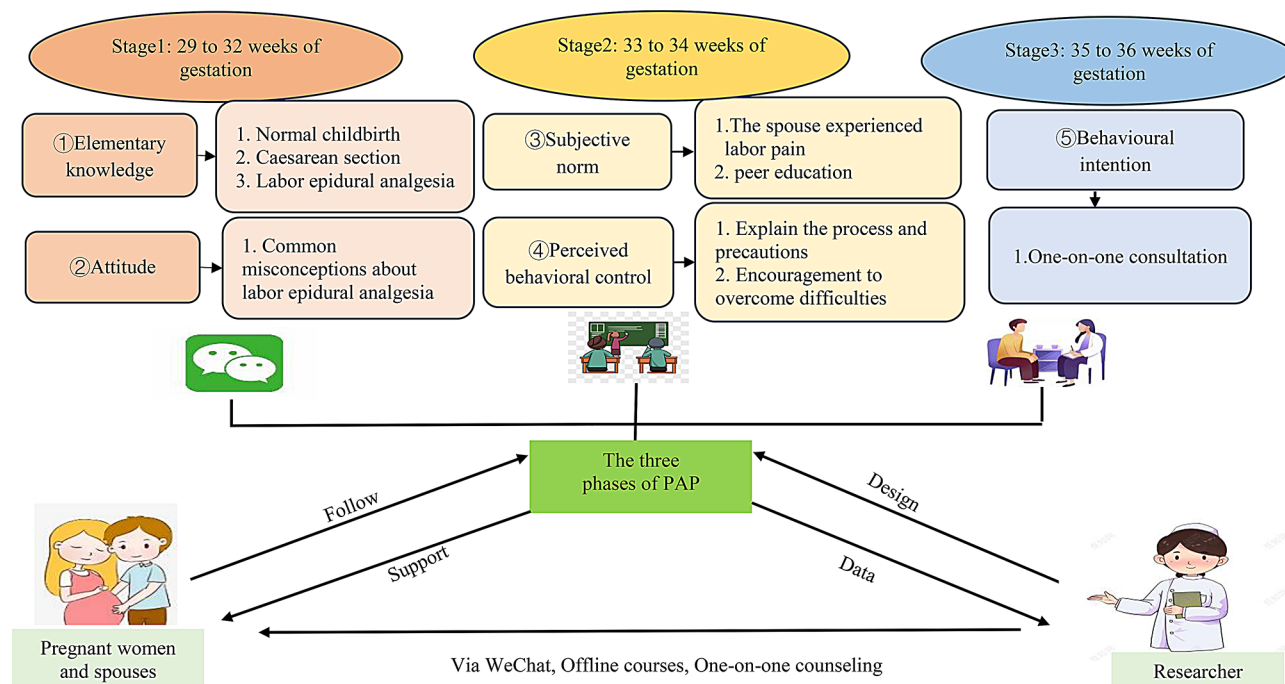
Secondary outcomes

The intention of LEA: it will be measured using the self-rating scale of Painless Delivery Intention based on the Theory of Planned Behavior (TPBT), developed for

Table 1 The details of the intervention

	Intervention Group	Control Group
Service	PAP + Routine care	Routine care
Provider	Researchers, Obstetricians, obstetric nurses	Obstetricians, obstetric nurses
Place	Web environment + Hospital	Hospital
Form	Internet + Face-to-face	Face-to-face
Contents	<ul style="list-style-type: none"> • The initial phase: <ul style="list-style-type: none"> – Elementary knowledge – Attitude • The second stage: <ul style="list-style-type: none"> – Subjective norm – Perceived behavioral control • The third stage: <ul style="list-style-type: none"> – Behavioral intention 	<ul style="list-style-type: none"> • Brochures and bulletin boards
Duration and frequency	<ul style="list-style-type: none"> • From the 29th week of pregnancy to the 36th week of pregnancy. The total intervention time is eight weeks. – In the first phase of the intervention, they were reminded to watch the content of the official account via WeChat or telephone every week. – In the second stage of the intervention, a face-to-face meeting lasting approximately 30 min to an hour will take place. – In the third stage of the intervention, one-on-one interviews lasting between 5 to 20 min will be conducted. 	<ul style="list-style-type: none"> • Distribution of education brochures. • Watch the bulletin board for yourself.
Assessment	<ul style="list-style-type: none"> • Baseline (pre-intervention) • Immediately after intervention • Assessment after delivery 	<ul style="list-style-type: none"> • Baseline (pre-intervention) • Immediately after intervention • Assessment after delivery

Abbreviations: PAP, an online and offline prenatal epidural labor analgesia education program

**Fig. 3** Intervention model of PAP

Chinese women to objectively judge the maternal behavioral intention of painless labor. The scale is a five-Likert self-rating instrument consisting of 30 items with a total score of 30–150. Greater scores correspond to a higher intention for painless childbirth among parturients. The scale's overall Cronbach's alpha coefficient was 0.971, the scale-level content validity index (S-CVI) was 0.984, and the item-level content validity index (I-CVI) was between 0.909–1.000 [34].

Fear of birth: Women's fear of birth will be assessed with the Simplified Chinese version of the Wijma Delivery Expectancy Questionnaire (W-DEQ-A-SC). This scale was initially developed by Swedish academic Klaas Wijma in 1998 and later underwent a process of cultural adaptation and validation by Chinese researchers in 2015 [36]. The scale consists of 33 self-report items across six dimensions: Positive Emotions (items 1, 13, 14, 18), Fear and Reactions (items 2, 6, 12, 17, 19, 24, 25, 27), Feelings of Helplessness (items 3, 7, 11, 15, 20), Risk Perception (items 31, 32, 33), Childbirth Cognition (items 9, 28, 29, 30, 21), and Self-Efficacy (items 4, 5, 8, 10, 16, 22, 23, 26). The scale total score ranges from 0 to 165 and applies to pregnant women during the gestational period of 28 to 41 weeks. The higher score equates to a greater fear of childbirth. The Cronbach's alpha coefficient of the scale in the Chinese version was 0.928, the content validity was 0.94, the test-retest reliability was 0.968, and the split-half reliability was 0.934 [36].

Misconceptions about LEA: The misperceptions of LEA will be evaluated with a 12-item questionnaire developed by Brandon M. Togioka [15]. The questionnaire includes 12 false statements about epidural analgesia. Primiparous women and spouses will be asked whether they agreed or disagreed with the statements. In this study, the researcher and another person proficient in English translated the questionnaire. If there were any disagreements, a third person would be consulted.

Data collection procedure

The baseline assessment will be conducted by the researchers, and each participant will be asked to complete the TPBT, W-DEQ-A-SC, epidural questionnaire, and social-demographic and clinical data in the obstetric clinic. A post-test will be conducted immediately after the intervention. Regardless of the reasons for withdrawal, we will make every effort to invite participants to complete the questionnaire to ensure data integrity. If face-to-face completion is impossible, all scales will be sent to participants via WeChat or email, and completed questionnaires will be returned to investigators via WeChat or email. The rate of LEA will be extracted from the electronic medical record during the postpartum period.

Data analysis

Data will be entered independently by two researchers and analyzed using the Statistical Package for Social Sciences 29.0 (SPSS 29.0). Intention-to-treat analysis (ITT) will be used to deal with missing data. The socio-demographic and clinical characteristics of primiparas will be presented as means \pm standard deviations (SDs) for continuous characteristics and frequencies and proportions for categorical characteristics. Two study groups will be compared regarding baseline characteristics using Chi-square (χ^2) tests and the independent sample t-test. If significant differences are found, these potential confounding factors will be adjusted for in the outcomes analysis. The primary outcomes (LEA rate) will be compared using Chi-square (χ^2) tests. Welch's t-tests will detect the secondary endpoint (Intention of LEA, Fear of Birth, and Misconceptions about LEA). We chose Welch's t-test to make our statistical inference more robust and avoid possible violations of standard model assumptions. *P* value of less than 0.05 will be considered statistically significant for all analyses.

Ethical considerations

Research ethical committee approval is obtained by the Research Ethics Committee of a tertiary hospital in Shenzhen (approval number KYLL-20231102 A). The registration number with the Chinese Clinical Trial Registry is ChiCTR2400079767. Ethical standards will be maintained throughout the whole process. There is no potential risk or harm in taking part in this program. Primiparous women will not be deprived of any treatment and routine care. Written informed consent will be obtained before data collection. Participants will be reassured that they have the right to withdraw from the study at any time without adversely affecting their pregnancy management. All of the collected data will be kept anonymously and confidentially.

Validity and reliability

This study uses a rigorous experimental design. This includes a scientific theoretical framework, high reliability and validity tools, and statistical scientific analysis. The composition of members of the study team reflects the collaboration of a multidisciplinary staff: obstetric and anesthesiology professionals provide knowledge and ensure accurate information on the conduct of this study. Professional statisticians, doctors of nursing science, and postgraduates can effectively ensure the quality control of the research process and the accuracy of data analysis, and clinical nurses are responsible for the organization and coordination of the department. To ensure the homogeneity of the intervention, we will provide standardized training to relevant members before the intervention and data collection to minimize bias.

Discussion

To our knowledge, there are no RCTs of prenatal primary care education with LEA rate as the primary outcome and online and offline combination as intervention models in mainland China. On the one hand, online intervention can have higher flexibility and accessibility. On the other hand, offline intervention can offer individualized medical consultation and humanistic care via face-to-face communication and support. Therefore, if PAP has positive outcomes, it will contribute to establishing a multifaceted educational model to support the popularization of LEA and reduce misconceptions regarding LEA.

This study also highlights the importance of early implementation of LEA education. Pregnant women in the right environment and time to obtain information reflects the people-centered healthcare philosophy. Implementation of LEA education in antenatal primary care can better complete this behavior. Even if the results are null, parturients will obtain more knowledge about LEA to promote equity in education and reduce the healthcare differences between parturients. If this study is effective, it will provide essential healthcare measures for prenatal analgesia education in mainland China and help promote informed decision-making for prenatal labor pain management.

Limitations

Some limitations need to be noted in the research. First, some potential biases could be caused by the lack of complete blinding of researchers during the whole research process, which would be impossible. Second, by the nature of health education, people interested in LEA are more likely to participate in this study, which may lead to potential selection bias. Last, this study is a single-center study due to the time and financial restrictions. The multicenter study should be carried out in the future and will be more representative.

Abbreviations

RCT	Randomized controlled trial
LEA	Labor epidural analgesia
PAP	Online and Offline Prenatal Epidural Labor Analgesia Education Program
TPB	Theory of Planned Behavior
ETPB	Extended Theory of Planned Behavior
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
W-DEQ-A-SC	Simplified Chinese version of the Wijma Delivery Expectancy Questionnaire
TPBT	Self-rating scale of painless delivery intention based on the theory of planned behavior
ITT	Intention-to-treat analysis

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12889-025-21562-5>.

Supplementary Material 1

Supplementary Material 2

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Author contributions

conceptualization: XZ, JW; methodology: XZ, JW; data collection: JC, WZ; data entry and analysis, JW, JC, WZ, JOY, JL; manuscript preparation: JW; manuscript revision: JW, XZ; project administration: XZ.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The study was approved by the Ethics Committee for Scientific Research of Shenzhen University General Hospital (Approval Number: KYLL-20231102 A).

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Roles and responsibilities

During the clinical implementation, the Scientific Research Ethics Committee of Shenzhen University General Hospital will supervise this study. Individuals who have obtained China GCP (Good Clinical Practice) certification will manage the study. Given that this study will not involve biological samples and will present minimal risk, a specialized Data Monitoring Committee (DMC) will not be established; instead, data management will be overseen solely by designated individuals.

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