Reproductive Health

STUDY PROTOCOL

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Design and implementation of interventions to improve unplanned pregnancy experiences: a mixed-methods study protocol with an interventional design

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Abstract

Background Unintended pregnancy, a pregnancy that have been either unwanted or mistimed, is a serious public health issue. The present study aims to design and implement interventions to improve unplanned pregnancy experiences.

Methods/design This exploratory sequential mixed method study will be conducted in three phases: qualitative, intermediate, and quantitative. The qualitative phase will use qualitative conventional content analysis with in-depth and semi structured individual interviews to explain and define the components and elements of pregnancy experiences of unplanned pregnancies, which include mothers with unplanned pregnancies, their spouses, and prenatal care providers, who will be selected purposefully. Additionally, in the initial phase, the study will employ literature reviews alongside qualitative findings to elucidate the components and elements of pregnancy experiences and their improving interventions. In the second phase, appropriate interventions (prioritized and feasible) will be determined through an expert panel using the Delphi technique. In the third phase, the intervention program agreed upon in the previous phase will be implemented in the form of a randomized controlled clinical trial.

Discussion The implementation of the interventions could be beneficial in changing attitudes and achieving positive experiences in unplanned pregnancies. It is anticipated that the design and implementation of the intervention program aimed at improving the experiences of unplanned pregnancies will be effective in minimizing adverse maternal and neonatal outcomes.

Trial registration Iranian Registry of Clinical Trials (IRCT): (IRCT20170506033834N12/Date of registration: 2024-02-12)

Keywords Unplanned pregnancy, Mixed-methods design, Pregnancy experience

Plain Language Summary

Unplanned pregnancy refers to cases in which a woman does not desire pregnancy (unwanted) or intends to conceive at a later date (mistimed). Approximately one-third of pregnancies are unplanned. Unplanned pregnancies often lead to adverse outcomes for both mothers and infants. While pregnancy is often viewed as a positive life

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event, unplanned pregnancies are typically associated with significant challenges and negative experiences. These mothers experience higher levels of anxiety and depression. Another negative consequence of unplanned pregnancy is a weak maternal–fetal attachment. Despite limited research on the experiences of women facing unplanned pregnancies, a comprehensive interventional study addressing their specific needs and aiming to improve outcomes was not identified in the literature review. To address this research gap, the study aims to design and implementation the intervention program designed to improve the experiences of unplanned pregnancies. The findings of this study can contribute in changing attitudes, achieving positive pregnancy experiences, and reducing adverse pregnancy outcomes.

Background

Unplanned pregnancy is a type of pregnancy that was neither desired by the woman and her partner nor planned for in the future (unwanted) or was considered to occur at an inconvenient time (mistimed) [1]. It is estimated that each year, there are 200 million pregnancies worldwide, approximately one-third of which, meaning 75 million cases, are unplanned. Of these, 50 million unplanned pregnancies are terminated annually [2, 3].

An unplanned pregnancy can occur among women of any social, demographic, and economic background, and nearly all women of childbearing age are at risk [4]. However, various factors influence the reduction or increase in the rate of unplanned pregnancies. Reports indicate that women with low incomes are four times more likely to experience unplanned pregnancies compared to women with higher incomes [5]. Additionally, studies have identified several factors influencing the increased rate of unplanned pregnancies, including young age (under 20 years) or old age (over 35 years), lower educational levels, a history of unplanned pregnancies and abortions, mental health issues, substance abuse, alcohol consumption, and sexual violence [6–8].

Although pregnancy is generally considered a pleasant event for families, this is not the case with unplanned pregnancies, which are often associated with unpleasant experiences [9, 10]. Unplanned pregnancy is an unexpected event that imposes responsibilities beyond the mother's capacity and, in cases where it leads to an induced abortion, if the abortion is illegal and unsafe, even result in the mother's death [11]. The consequences of unplanned pregnancy—whether it leads to an induced abortion or continues—are serious and pose significant problems for the mother, the partner, and, if the pregnancy continues, for the child. Evidence indicates that unplanned pregnancies have more negative impacts on women's lives and fetal health compared to planned pregnancies [7, 12, 13].

Women with unplanned pregnancies experience higher levels of anxiety and depression [14]. In women with unplanned pregnancies, the likelihood of experiencing depression during the prenatal period and postpartum is 2.5 times higher [15]. These psychological disorders negatively affect the ability to perform the role of a mother [16]. Depression during pregnancy can lead to the avoidance or delay of prenatal care, inadequate nutrition, smoking, and the use of alcohol or other harmful substances during pregnancy [17]. One of the most prominent characteristics of postpartum depression is the rejection of the newborn, often resulting from the mother's abnormal anger and frustration. Postpartum depression increases the risk of child mortality, behavioral problems in adolescents, and the likelihood of developing depression in adulthood among these children by 3 to 5 times compared to other children [18, 19].

Another irreparable harm of unplanned pregnancies is the weakening and delay in the development of mother-infant bonding [20]. Weak interaction between the mother and the fetus impairs the child's cognitive development and growth [21, 22]. Additionally, weak bonding between the mother and the newborn is associated with negative outcomes such as inadequate care, preterm birth, low birth weight, increased risk of neonatal death, and neglect of the initiation and continuation of breastfeeding [23, 24].

In 2018, the World Health Organization (WHO) published a set of general recommendations aimed at improving the quality of planned pregnancy care and optimizing maternal and neonatal outcomes. They defined a positive pregnancy experience as maintaining normal physical, social, and cultural conditions and ensuring a healthy pregnancy for both mother and child (including the prevention or treatment of risks, illness, and death). Additionally, it involves a positive transition to labor and delivery and a successful attainment of motherhood (which includes maternal self-esteem, competence, and autonomy) [25]. According to evidence, a "positive pregnancy experience" for women is achieved through five components in prenatal care: nutritional interventions, maternal and fetal assessments during pregnancy, preventive measures, interventions for common physiological symptoms, and health system interventions to improve the utilization and quality of prenatal care [26].

In global studies, the issue of unplanned pregnancy is particularly challenging concerning adolescents [27–29] and among married women, it is less challenging in non-Islamic societies compared to Islamic societies due to fewer legal restrictions and a greater emphasis on women's right to choose over the fetus's right to life [30] and the presence of options such as the adoption of unwanted children makes the challenge of mandatory continuation of unplanned pregnancies less prominent. Qualitative studies in this field have focused on the decision-making process regarding abortion or the continuation of unplanned pregnancies and the copping process to these situations [31–34]. However, studies related to the experience of pregnancy and the needs of women facing unplanned pregnancies are limited, and a comprehensive interventional study that leads to improved unplanned pregnancy experiences was not found in the literature review.

In Iran, concerns of policymakers over the past two decades regarding the declining population growth rate have led to the proposal of various plans and policies aimed at reversing this trend. The Family Protection and Youthful Population Support Law passed in 2021, includes supportive and incentive measures alongside various prohibitions and restrictions on the provision of contraceptives, sterilization, and induced abortion [35]. Under these circumstances, it is anticipated that the rate of unplanned pregnancies in the country may be on the rise.

Given the limited evidence-based information regarding appropriate interventions for improving unplanned pregnancy experiences, the present study aims to design (identify the components that improve pregnancy experiences) and implementation the intervention program designed to improve the experiences of unplanned pregnancies. Considering the different circumstances of unplanned pregnancies and the special needs of these mothers, as well as the limited evidence-based information on appropriate interventions for this group of women, it is expected that more and different interventions compared to planned pregnancies will be effective in changing attitudes, achieving positive pregnancy experiences, and reducing adverse pregnancy outcomes.

Objectives

The overall objective of this study is to design and implementation of interventions to improve unplanned pregnancy experiences.

Study design

The present research is an exploratory sequential mixed-method study. The exploratory sequential technique is an approach to combining qualitative and quantitative data collection and analysis in a sequence of phases [36]. In the first phase, researchers collect qualitative data and then analyze the data, the results of which direct the next, quantitative phase, which could be a survey or some other form of quantitative data collection. That is, the qualitative analysis provides critical fodder for developing specific research questions for the quantitative phase, which involve a questionnaire, survey, or other form of quantitative data collection [37].

This study will be conducted in three phases. In the first phase, qualitative research will be utilized to elucidate and define the components and elements of pregnancy experiences. This qualitative segment will involve a study using a conventional content analysis approach aimed at understanding the experiences of unplanned pregnancies from the perspectives of participants, including mothers with unplanned pregnancies, their spouses, and prenatal care providers (midwives and obstetricians with at least 2 years of experience), with in-depth and semi structured individual interviews, who will be purposefully selected. In the first phase, in addition to the findings from the qualitative study, literature reviews will also be used to clarify the components and elements of unplanned pregnancy experiences and interventions to improve them.

In the second phase, intervention design will be conducted through an expert panel using the Delphi technique. The experts involved at this stage will include specialists in reproductive health, Ph.D. in midwifery, obstetricians, and health managers with at least 5 years of experience.

In the third phase, a randomized controlled clinical trial will be conducted to determine the impact of the designed intervention program on the experiences of unplanned pregnancies. This will take place after obtaining an ethical code and registering the trial with the Iranian Registry of Clinical Trials (IRCT). During this phase, sampling of eligible mothers for participation in the study will be performed using a convenience sampling method.

Participants will be provided with comprehensive information about the research, its objectives, and the implementation methods. If they agree to participate, informed written consent will be obtained, and participants will be assured of the confidentiality of their information (Figs. 1 and 2).

Study phases

Qualitative phase (phase 1)

Study design

The study will employ a conventional content analysis approach. In the current study, data regarding the components affecting pregnancy experiences are available in existing sources and literature, but specific data on the experiences of unplanned pregnancies were not found.

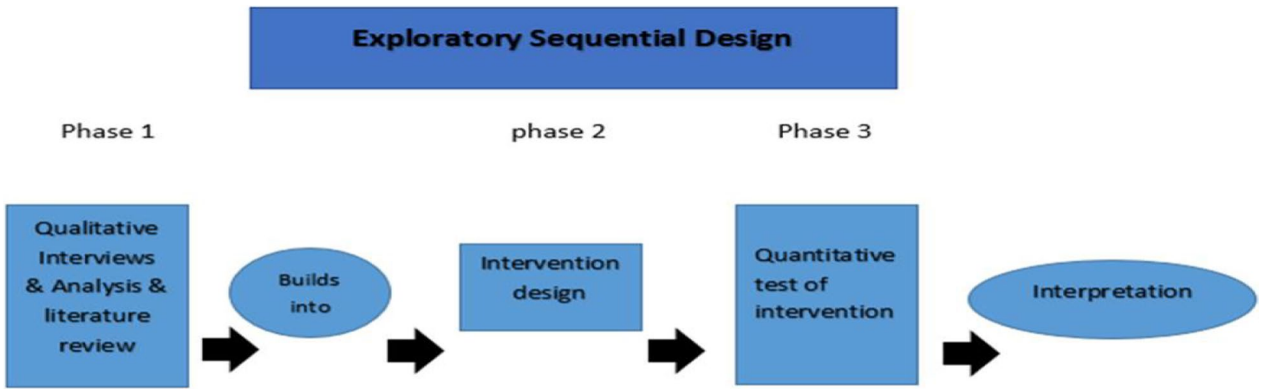

Fig. 1 Study visual diagram

Specific objective

Elucidating the experiences of unplanned pregnancies through qualitative research and literature review.

Inclusion criteria

1. Women with unplanned pregnancies.
2. Partners facing unplanned pregnancies.
3. Age range: 18 to 45 years.
4. Residents of Tabriz.

Exclusion criteria

1. Chronic or exacerbating physical illnesses during pregnancy.
2. Known psychological disorders as reported by the mother.

Sample size and sampling method

Participants will be selected using purposive sampling. In this method, the most diverse or knowledgeable respondents relevant to the study topic will be chosen. The primary participants in this study will be mothers with unplanned pregnancies. However, interviews will also be conducted with their partners and prenatal care providers, including midwives and obstetricians.

The sample size for this phase will continue until data saturation is achieved. Saturation occurs when no new or relevant data emerges, and the development of a category reaches a satisfactory level of diversity.

Data collection

For qualitative data collection, after obtaining informed consent, in-depth, semi-structured individual interviews will be utilized. The interviews will start with open-ended questions. For instance, the interview questions for women and their partners will include:

- When you became aware of this pregnancy, how did you feel?
- What challenges have you faced in dealing with this pregnancy? (concerns and worries)
- Can you describe your experiences with this pregnancy?
- What measures do you think could improve your experiences and conditions related to this pregnancy?
- Under what circumstances would continuing the pregnancy be more pleasant to you?
- What expectations do you have from our healthcare staff in terms of their support during this period? How can we assist you until delivery?

Questions for interviews with midwives and obstetricians will include

- Can you describe your experiences in providing care for women with unplanned pregnancies?
- In your opinion, what are the key challenges and needs of women and their partners when facing an unplanned pregnancy?
- As a midwife or obstetrician, what specific actions do you take to improve the experiences of women with unplanned pregnancies?

As the interview progresses, exploratory questions related to the study's objectives will be introduced. The interviews will be recorded with the participant's consent, and the timing of the interviews will be chosen based on the participants' preferences and agreement. During the interviews, the researcher will document observations of the participants' non-verbal reactions and behaviors

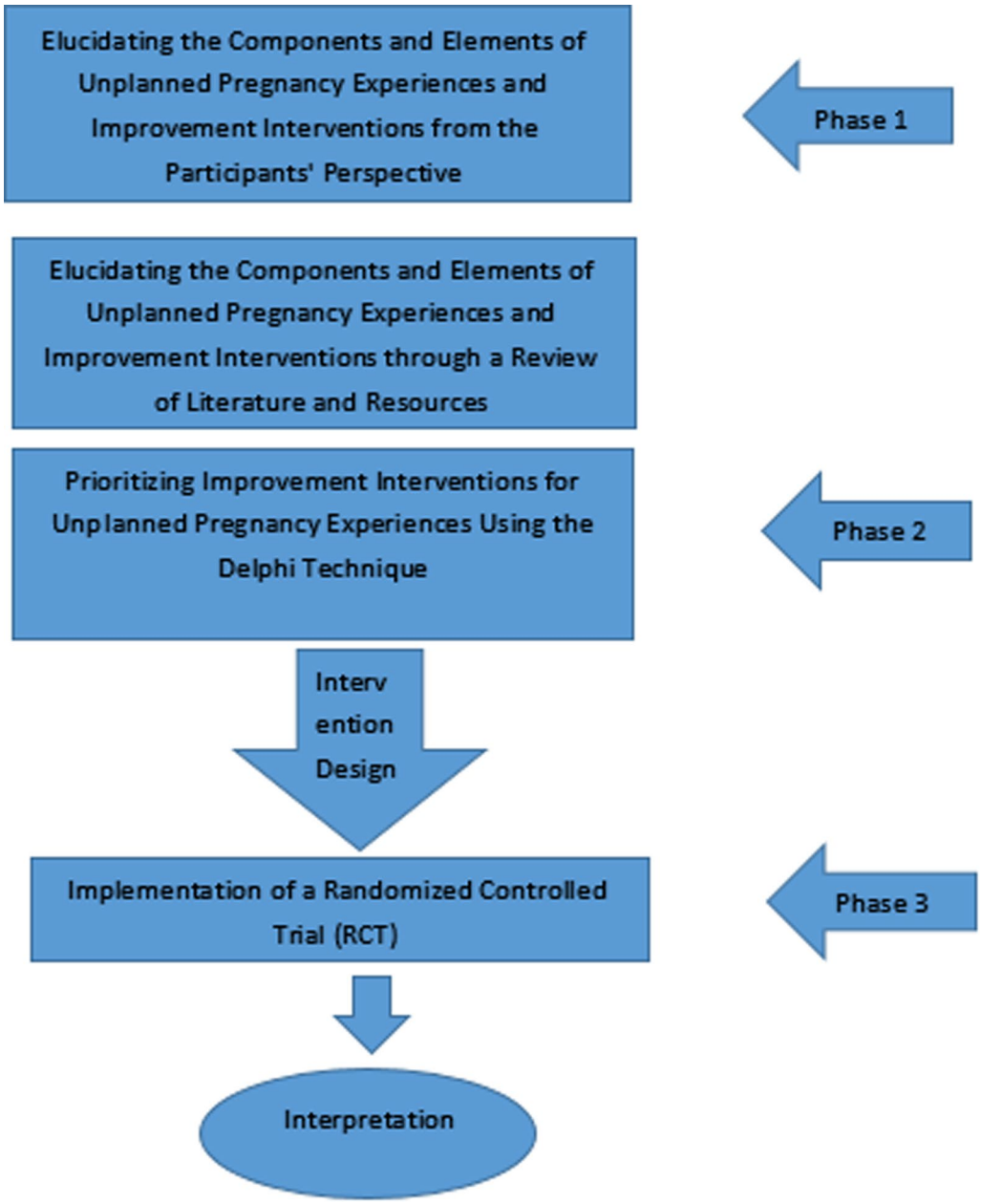

Fig. 2 The process of the study

(such as facial expressions, tone of voice, emotions, and reactions like laughter, crying, and pauses), as well as other significant occurrences and points from each interview session. These notes will be used in the data analysis process.

Analysis

In this study, qualitative content analysis using a conventional approach will be employed for data analysis. The main advantage of qualitative content analysis based on the conventional approach is obtaining direct information from the study without imposing predetermined categories or theories [38]. In this research, conventional content analysis will be conducted following the steps proposed by Graneheim and Lundman [39] .This method allows for accessing not only the manifest content of interview texts but also the latent content and concepts with varying levels of abstraction. Therefore, based on this method, the following five steps will be undertaken:

1. Transcribing the entire interview immediately after each interview.
2. Reading the entire text multiple times to gain a general understanding of its content.
3. Dividing the text into meaningful units, extracting summaries of meaningful units, and coding.
4. Classifying initial codes into subcategories and categories based on comparing similarities and differences.
5. Extracting themes as representations of concepts and hidden content in the data.

To analyze the data, after the completion of each interview session, the researcher will listen to the recorded file at the earliest possible opportunity. All content, along with the notes taken during the interview, will be transcribed verbatim. To enhance the accuracy of the obtained information, the interviews will be listened to multiple times by the researcher and will be cross-checked with the transcriptions. The transcribed interviews will then be transferred to MAXQDA software version 2020 for analysis. Each interview will be analyzed before the next interview is conducted.

Literature review

Specific objective Review of scientific literature on components and factors of pregnancy experiences and interventions for improving pregnancy experiences.

Data collection According to the study question "What are the components and factors of pregnancy experiences and interventions for improving these experiences based on literature and sources?" based on the PICO criteria, relevant sources and studies will be searched without time limitations in English and Persian databases including PubMed, Scopus, Embase, Web of Science, Cochrane Library, SID, Magiran, Iran Doc, and the Google Scholar search engine. The search components will be specified according to population, intervention, comparison and outcomes (PICO), and then related and synonymous keywords will be searched. All quantitative studies (observational, interventional, meta-analyses, and review studies), qualitative studies, and mixed-method studies will be examined.

Inclusion criteria

1. Articles published in journals.
2. Availability of full text of the articles.
3. Presence of relevant keywords in the article.

Exclusion criteria

1. Duplicate and irrelevant articles.
2. Articles published in languages other than English and Persian.

Combining data from qualitative research with a literature review

After extracting codes through the literature review, interviews, and integrating findings from both stages, a draft will be prepared outlining the reported needs and improvement strategies for enhancing the experiences of unplanned pregnancies.

Intermediate phase (phase 2)

Specific objective

Determining improvement strategies for unplanned pregnancy experiences according to experts using a Delphi panel.

Data collection

The Delphi method focuses on gathering expert opinions within a short period and the results depend on the expertise of individuals in the relevant field, the quality and accuracy of responses, and their continuous engagement and collaboration throughout the study [40]. In this research, Delphi panel members (reproductive health specialists, Ph.D. in midwifery, obstetricians, and health managers with at least 5 years of experience) will be selected based on purpose. In this phase, the information obtained from the first phase (qualitative study and literature review) will be combined and prioritized for feasibility through two rounds of surveys with the panel of experts. Since the validity of Delphi relies not on the number of participants but on the scientific credibility of the experts involved, Delphi study participants are usually fewer than 50, most commonly between 12 and 20 [41]. In the present study, 20 people will be selected as expert panel.

Implementation of Delphi phase 1

In this phase, the improvement items for unplanned pregnancy experiences are introduced to the experts and explained to them. The goal of this phase is to obtain expert opinions on the proposed solutions, whether each solution is placed correctly and appropriately, and how feasible the designed protocol is. The initial protocol will be provided to the experts for prioritization through a survey form sent via email. Each solution's priority will be rated by the experts on a scale from one (lowest priority) to four (highest priority). After receiving the survey forms, the analysis will be performed quantitatively by

calculating the mean and standard deviation of the scores for each solution. The mean scores will be computed using SPSS version 25. Based on the results, items with scores less than 2.5 will be removed from the protocol, while items with scores of 2.5 and above will be recognized as agreed upon and will be listed based on higher mean scores and lower standard deviations [42].

Implementation of Delphi phase 2

This round of Delphi consultation is conducted to review the results from the first round of the Delphi survey. This round aims to validate or assess the importance, scientific acceptability, and feasibility of the proposed initial protocol. In this phase, the protocol will be designed in the form of a survey containing the final indicators of the protocol. This form will be electronically sent via email to the experts who participated in the first round of Delphi, and they will be asked to provide their opinions on each solution individually, using a scale of low (1), medium (2), and high (3). Descriptive statistics and SPSS version 25 will be used to analyze how the solutions in the protocol are rated. Solutions with low feasibility will be removed. Qualitative comments will also be analyzed. Finally, the protocol for improving unplanned pregnancy experiences will be developed, validated, and finalized by the research team based on this feedback.

Quantitative phase (phase 3)

Specific objectives

Comparison of the mean scores of pregnancy experiences between intervention and control groups at 35–37 weeks of gestation.

Sampling

In this phase, a randomized controlled clinical trial will be conducted to determine the impact of the designed intervention program on unplanned pregnancy experiences. The target population will consist of women aged 18 to 45 with unplanned pregnancies who visit healthcare centers in Tabriz during 2024. In this stage, sampling will be conducted from mothers meeting the criteria to participate in the study using a convenience sampling method. Participants will then be provided with detailed explanations about the research, its objectives, and the implementation method.

In this study, pregnancy experience will be measured as the primary outcome. To allocate participants to the study groups, a randomized block design will be used, with blocks of four and six, and a 1:1 allocation ratio, stratified by the type of unplanned pregnancy (unwanted or mistimed). To ensure allocation concealment, the type of intervention will be written on paper and placed inside opaque envelopes, numbered consecutively. The envelopes will be opened by an individual not involved in the sampling process to determine the type of intervention received. Figure 3 shows the flowchart of this phase.

Inclusion criteria

1. Women with unplanned pregnancies above gestational age of 16 weeks of pregnancy.
2. Maternal age 18–45 years.
3. Singleton pregnancy.
4. Viable fetus.

Exclusion criteria

1. Vaginal bleeding (threatened miscarriage).
2. Previous history of depression as reported by the mother.
3. Presence of maternal or fetal indications for termination of pregnancy.
4. Conflict with the partner.

Scales and data collection

To collect quantitative data, a Personal-Social and Obstetric Information Form and the Pregnancy Experience Scale (PES) will be used.

The personal–social information form

The Personal–Social Information Form will include details such as the age and education level of the participant, age and education level of the spouse, employment status, family economic status, number of pregnancies and deliveries, number of miscarriages, gestational age, and other relevant information. This form will be completed upon the participant's entry into the study.

Pregnancy experience scale

PES is designed to measure mothers' experiences during pregnancy. This scale consists of 20 items divided into two domains: worry and joy during pregnancy. The scale includes ten items focused on worry (e.g., how much each item causes concern and distress for the pregnant mother) and ten items focused on joy (e.g., how much each item contributes to happiness and pleasure for the pregnant mother). For each item, a four-point Likert scale is used, ranging from "Not at all" to "Very much," with corresponding scores of 0 to 3. Higher scores indicate greater levels of worry or joy [43]. In the Iranian version of the tool, Cronbach's alpha coefficient for the

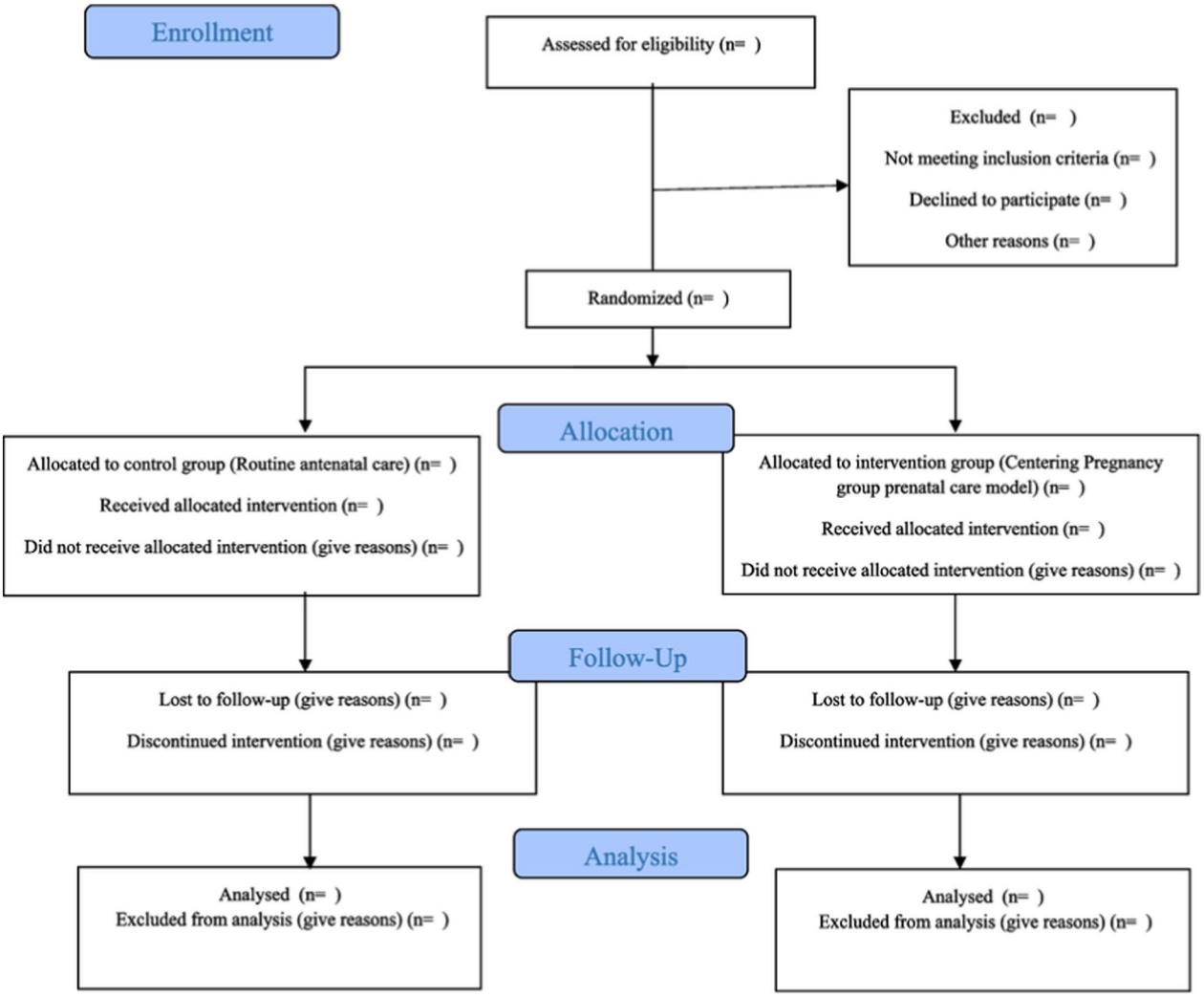

Fig. 3 Consort flowchart of the trial process

entire scale was 0.714, and the intraclass correlation coefficient was 0.721 [44].

Sample size

In this study, the sample size was determined using the G-POWER software. Based on the study by Kia et al. [45], and considering m1 = 41.8 and assuming a 20% increase in pregnancy experiences with m2 = 50.16, and with sd1 = sd2 = 10.22, and a test power of 80% with a two-tailed test for the pregnancy experience variable, the sample size was calculated to be 25 participants per group. Taking into account a 20% dropout rate, the final sample size for each group was adjusted to 30 participants.

Analysis

In this stage, the data will be analyzed using SPSS version 25. The normality of data distribution will be assessed using the Shapiro–Wilk test. Descriptive statistics will be employed for summarizing individual and social characteristics. For qualitative variables, frequencies (percentages) will be reported, while for continuous variables, means and standard deviations will be used if the data distribution is normal, and medians with interquartile ranges (25th to 75th percentiles) will be used if the distribution is non-normal.

To compare quantitative variables between study groups before the intervention, ANCOVA will be used, controlling for the stratification factor. After the intervention, ANCOVA will again be used, controlling for baseline scores and the stratification factor. Missing data will be managed using multiple imputation

techniques. All analyses will be conducted based on the intention-to-treat principle.

Discussion

The importance of fertility as a major factor in demographic structure has led to fertility studies holding a special place in demographic research. Although pregnancy is generally considered a positive event for families, the situation is different when it comes to unplanned pregnancies, which are often accompanied by unpleasant experiences. The mismatch and lack of acceptance of an unplanned pregnancy can lead to reduced parental responsibilities, unhealthy behaviors during pregnancy such as alcohol, drug, and cigarette use, risky sexual practices, inadequate sleep and rest, compared to women with planned pregnancies. Many of these women do not pay adequate attention to their nutrition during pregnancy. Additionally, many of them do not receive sufficient amounts of essential nutritional supplements, including folic acid and micronutrients during pregnancy [2]. Unplanned pregnancies are associated with an increased risk of complications such as anemia, preeclampsia, urinary infections, and gestational diabetes for mothers [46].

Therefore, maternal physical health during pregnancy is seriously jeopardized by unplanned pregnancies. In addition to physical complications, unplanned pregnancies lead to psychological and emotional problems in women and psychological stress in men. Women facing unplanned pregnancies often experience negative emotions and are at risk of developing neurotic symptoms such as aggression, sleep disturbances, and nightmares. In situations where mothers expect enjoyable experiences with the birth of their baby, they may instead face unpleasant states such as anxiety, weakness, lack of pleasure, sleep and appetite disorders, lack of self-confidence, and feelings of inadequacy as parents [47, 48]. Mohammadi et al., in their qualitative study, categorized women's experiences with unplanned pregnancies into four themes: disbelief and negative emotional responses, fragile and unstable justification, perceived support, and conflicts following the decision to terminate or continue the pregnancy [49].

In a study conducted by Lattof et al. [50], the antenatal care areas related to positive pregnancy experiences were categorized into the following three main areas: health system, Content of care and experience of care (management of physiological symptoms).

Based on the results of the reviewed studies, only one qualitative study [51] on unplanned pregnancy experiences has been conducted. The extracted themes from this study do not contribute to identifying the components that could enhance the experience of women with unplanned pregnancies. The limitation of evidence-based information regarding appropriate intervention methods for this group of women highlights the need for comprehensive and high-quality research in this area to improve pregnancy experiences.

Strengths and limitations

Our study is the first global research focused on designing interventions to improve experiences for women with unplanned pregnancies. In the qualitative phase of this study, the most diverse respondents (based on the trimester of pregnancy, whether the pregnancy was unwanted or mistimed, and demographic characteristics) or the most knowledgeable individuals regarding the study topic will be selected. In the quantitative phase, standardized tools will be used to measure pregnancy experiences, which are considered strengths of the study. However, limitations include specific characteristics of the research population, such as religious and legal restrictions on abortion in Iran, which may affect the generalizability of the research findings.

Conclusions

It is anticipated that the results of this study will contribute to creating a positive experience by implementing effective interventions for unplanned pregnancies, thereby improving quality of life and maternal-infant outcomes.

Funding

This study is funded by Tabriz University of Medical sciences. The funding source had no role in the design or conduct of the study, nor in the decision to write or submit this manuscript.

Abbreviations

WHO	World Health Organization
PICO	Population intervention comparison outcomes
PES	Pregnancy Experience Scale

Acknowledgements

We would like to express our gratitude to the Vice-Chancellor for Research at Tabriz University of Medical sciences for their financial support.

Author contributions

Authors 1, 2 and 5 contributed to the design of the protocol. Author 1 and author 2 will be involved in the implementation of the protocol. Authors 1, 3 and 4 will conduct data entry, and data analysis. Author 1 and author 2 also wrote the first draft of this protocol article. All authors critically reviewed the text, provided inputs and revisions, and approved the final manuscript.

Availability of data and materials

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent of participants
The study followed ethical guidelines, including the Helsinki Declaration and received approval from the ethics committee of Tabriz University of Medical Sciences (ID: IR.TBZMED.REC.1402.740). Informed written consent will be obtained from participants in both the qualitative and quantitative phases.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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Received: 2 October 2024 Accepted: 11 October 2024
Published online: 28 October 2024

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