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A mixed methods study protocol to develop an educational program based on salutogenesis theory to improve the postpartum quality of life among nulliparous women

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Research on postpartum quality of life (QoL) often focuses on preventing adverse health outcomes rather than promoting positive health and well-being (salutogenesis). While Salutogenesis theory (ST) has been shown to enhance the sense of coherence (SOC), its application in pregnancy and childbirth is limited. This paper presents a mixed-methods protocol for developing a salutogenic educational program to improve postpartum QoL and maternal health outcomes. Data will gather from healthcare centres in Ahvaz city, Khuzestan province, Iran. In the first phase (qualitative approach), nulliparous women's experiences of determinants of postpartum QoL will be explored by semi-structured in-depth interviews. In the second phase literature review will be conducted to identify factors which affected postpartum QoL. In the third phase, the content of the educational program will be developed. In the fourth phase (a Randomized Controlled Trial), 110 nulliparous women will be randomly allocated to intervention and control groups using blocked randomization. Two groups will be compared in terms of primary and secondary outcomes by validated instruments at baseline, immediately after the intervention, 4 weeks, and 8 weeks after delivery.

Keywords Mixed method study, Educational program, Salutogenesis, Sense of coherence, Quality of life, Postpartum

Postpartum period is a challenging transition in a woman's life[1]. Changes in parental roles[2], family relationships[3], and self-perception are also common postpartum psychosocial adaptations[4]. A woman is more susceptible to health problems during the year following childbirth due to these transitions, coupled with the physical recovery from childbirth and the efforts required to meet the needs of a newborn. It has been shown that unabated stressors of the postpartum period can result in anxiety, fatigue, and decreased self-care and QoL[3,4]. These factors may raise the risk of physical and mental illness, including postpartum depression[4]. Consequently, maternal mental and physical health problems increase the likelihood of a multitude of negative health outcomes for the entire household, such as early breastfeeding discontinuation, negative perception of the infant by the mother, delayed language acquisition, compromised attachment between mother and child, a decrease in childhood vaccinations, and an increase in behavioural problems among children[4,5]. Studies have shown that one of the important aspects of postpartum period is the postpartum QoL[3,6]. Poor postpartum adjustment can reduce the maternal QoL[7].

Postpartum QoL is also negatively affected by demographic characteristics[8], insufficient social support, heavy workloads, husband's limited involvement in household affairs[9], financial problems, fatigue[8], postpartum

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depression[10], sexual dysfunction[11], delivery method[9], and complications related to pregnancy[8]. It has been demonstrated that socio-cultural context has a direct impact on the QoL[12].

Studies show that adequate education during pregnancy improves women's QoL[13,14]. To develop effective educational interventions for birth and postpartum issues, it is essential to identify the women's educational needs[15,16]. This is despite the emphasis on considering the needs of pregnant women in educational programs, a large portion of prenatal education focuses on pathology, which shows the causes and effects of diseases[17]. Pathogenesis perspective identifies and solves health problems. Alternatively, Salutogenesis approach focuses on achieving a state of optimal health in order to promote well-being[18,19]. It encourages healthcare providers to offer health-focused prenatal care to help women achieve an optimal state of health[17,18]. The ST was proposed by Aaron Antonovsky in the 1970s as a way to explain how people deal with stressful situations[20]. A major focus of this theory is on identifying the most important protective factors that are needed to maintain health and stability during stressful periods and provides a solution for understanding health status, ranging from very good to very poor[20].

In the ST, the two main concepts which underpinning it are "Generalized Resistance Resources" (GRRs) and SOC. GRRs can be applied to a wide range of stressors or demands[20]. In the absence of GRRs, dealing with stressors is usually difficult[21]. SOC is an indicator of an individual's ability to deal with stressful situations by using available and potential resources. An individual's understanding of manageability, comprehensibility, and meaningfulness constitutes the concept of SOC[20]. A person who feels that stressors and life situations are predictable and explainable is referred to as comprehending; manageability indicates that they feel as though they are using the necessary resources to cope with stressors; and meaningfulness refers to the motivations that arise from the emotional meanings of valuable investments in response to life challenges[20,21].

With regard to the behavioral mechanisms, a strong SOC allows one to identify and mobilize GRRs in order to cope with stressful exposures. In addition to individual characteristics, GRR is influenced by a variety of external factors[22]. Higher GRR levels are associated with positive views concerning stressful encounters and one's ability to cope with them. Therefore, they are capable of influencing perceptual mechanisms in a positive manner. There is a possibility to increase inner strength through interventions that focus on increasing awareness (perceptual mechanisms) and the ability to mobilize (behavioral mechanisms) the GRR[23].

Research indicates that Salutogenic health promotion programs can enhance SOC[24–26]. However, the use of this theory in pregnancy and childbirth has been limited, particularly in development of health education programs[18]. A small number of studies in the field of childbirth that reference the ST suggest that women possess a strong SOC are more likely to practice healthy behaviours, such as refraining from smoking, seeking out supportive services, and enjoying enhanced emotional health with reduced levels of stress, depression, and anxiety. The likelihood of an uncomplicated delivery is higher for women with strong SOC, and vaginal delivery is the preferred option for these women[19,27–29]. Furthermore, women with a strong SOC were half as likely to undergo caesarean section as those with a weak SOC[27,29], had more positive, calm, baby-focused attitudes and were more satisfied with their delivery, regardless of the method of birth[27,29,30].

This theory might make a difference to the current pathogenesis model of prenatal care[31]. ST hypothesizes a wide range of QoL, ranging from high to very poor with A high level of SOC is associated with high QoL[20,32]. There is evidence that improving SOC can result in improved postpartum QOL, as it reduces the stress and anxiety that mothers experience, and allows them to improve their health conditions[33].

In a variety of studies, conflicting results have been reported regarding the effects of educational interventions on postpartum QoL[34,35]. Evidence is insufficient to support the hypothesis that prenatal childbirth education can prevent postpartum depression, or enhance couple relationships, and postpartum QoL[36]. There is substantial evidence that prenatal education classes are important in improving the postpartum QoL[35]. A study suggests that home visits and training programs can improve postpartum QoL[37]. Further, a number of recent studies have indicated that postpartum self-care based on the Teach Back method[38], progressive muscle relaxation[39], diet intervention[40], as well as aerobic water exercise[41] may result in an improvement in postpartum QoL.

Women in Iran experience a poor QoL during the postpartum period, particularly during the first three months after childbirth[42,43], which further highlights the necessity of appropriate interventions in Iran[43]. Though a large body of evidence indicates that SOC and QoL are positively associated, few studies have examined the effects of using ST in antenatal education on pregnant women[18,28].

This study aims to design, implement and evaluate an educational program based on ST to improve the postpartum QoL among nulliparous women. For this purpose, we will explore the perceptions of primiparous women regarding postpartum QoL. We will also review the determinants of postpartum QoL in literature to identify the main factors affecting postpartum QoL and describe the concepts of ST in this regard. Then, we will implement and evaluate this salutogenic educational program.

Methods

The study will be conducted in four phases utilizing an exploratory sequential mixed methods design (Fig. 1):

1. First phase: Qualitative study.

   Objective: Explaining primiparous women's experiences of determinants of postpartum QoL during their postpartum period.

2. Second phase: Review Study.

   Objective: Identifying the factors affecting the postpartum QoL among primiparous women.

3. Third phase: Nominal Group Technique (NGT).

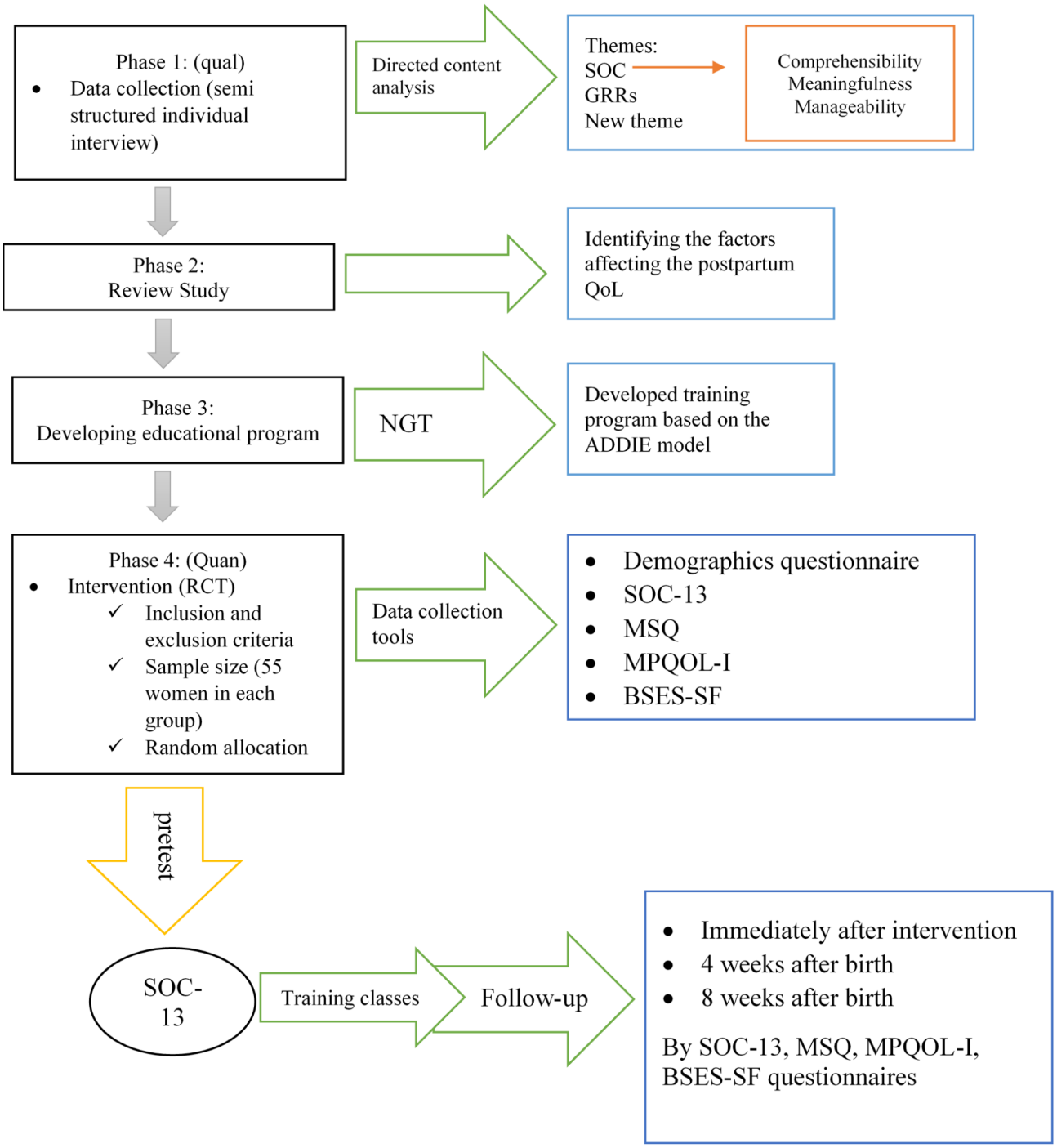

Fig. 1. Diagram of the study.

Objective: Developing an educational program based on the first and second phases.

4. Fourth phase: Quantitative study (Randomized Controlled Trial (RCT)),

Objective: Implementation and evaluation of the developed educational program.

4.1. Primary Specific Objective:

- To compare the postpartum QoL among study groups 4 and 8 weeks after delivery.

4.2 Secondary Specific Objectives:

- To compare the SOC among study groups before intervention, immediately after intervention, as well as 4, and 8 weeks after delivery.
- To compare the rates of vaginal delivery among study groups.
- To compare the maternal self-efficacy among study groups 4 and 8 weeks after delivery.
- To compare the breastfeeding self-efficacy among study groups 4 and 8 weeks after delivery.

It is noteworthy that the objectives of the fourth phase may be changed based on the qualitative phase.

Research questions and hypotheses.

1. Qualitative study.

   What are the influencing factors that affect the postpartum QoL in primiparous women?

2. Review Study.

   Which factors are effective on postpartum QoL among primiparous women?

3. NGT.

   What should be the content and characteristics of the educational program?

4. Quantitative study (RCT) (Table 1).

- The implementation of the educational program based on the ST can enhance the postpartum QoL.
- The implementation of the educational program based on the ST can enhance the SOC.
- The implementation of the educational program based on the ST has an effect on the mode of delivery.
- The implementation of the educational program based on the ST can enhance the maternal self-efficacy.
- The implementation of the educational program based on the ST can improve the breastfeeding self-efficacy.

First phase: a qualitative exploration

Primiparous women in the postpartum period will be selected through purposeful sampling method from the healthcare centres in Ahvaz, Iran. A semi-structured in-depth interview with open-ended questions will be used to collect qualitative data. To achieve the maximum variation, women will be selected from a wide range of age groups, educational levels, employment and socioeconomic statuses (Table 2). Inclusion criteria are primiparity, at least 18 years of age, being able to speak and understand Persian language, being in postpartum period (up to eight weeks after delivery). Sampling will continue until saturation of data is reached, that means no new code emerged. Finally, several additional interviews will be conducted to ensure accuracy.

Data collection method.

A brief explanation of the research objectives will be provided verbally to participants prior to the start of the interview. As well, individuals will be explained their right to answer questions and participate in the research, as well as their right to withdraw from the study at any time. A number of open-ended questions will be used. It is preferred that the interviews be conducted in a calm, comfortable and accurate environment without any time constraints. Participants will determine the time and location of the interview. Participants will be interviewed for as long as necessary in order to gain an understanding of their experiences and to provide in-depth responses. A Ph.D. candidate in midwifery who has completed qualitative research methodology courses will conduct interviews.

Prior to the qualitative phase, interview guide questions are prepared based on the ST construct and concepts, as well as opinions of experts. A pilot interview will be conducted after the questions have been drafted to determine whether the objective of the qualitative phase can be achieved by the use of these questions. Researchers may rewrite the interview questions if necessary. Finally, a guide for conducting interviews will be developed. Some preliminary interviews will be conducted as a pilot in order to familiarize the researcher with possible and unforeseen issues.

According to ST constructs, the following open question will be asked first: " Are you satisfied with your life?“, " In general, what is your imagination about postpartum life?” (comprehensibility), " How do you feel about motherhood? Talk about your feeling.” (meaningfulness), " What do you do when you get confused and can’t do your tasks?” (manageability), and " How did the behaviour of your husband, your family, your friends,

Question	Hypothesis (if applicable)	Sampling plan (e.g. power analysis)	Analysis plan	Interpretation given to different outcomes
How does a salutogenic educational program affect postpartum quality of life (QoL) and maternal health outcomes in nulliparous women?	Implementing a salutogenic educational program will significantly improve postpartum QoL and maternal health outcomes compared to the control group	110 nulliparous women in Ahvaz city, Khuzestan province, Iran, will be selected according to eligibility criteria and then randomly allocated to intervention and control groups using blocked randomization	Primary and secondary outcomes will be compared between the two groups using validated instruments at baseline, immediately after intervention, 4 weeks, and 8 weeks post-delivery	An increase in postpartum QoL and improved maternal health outcomes in the intervention group will indicate the program’s effectiveness, while no significant difference or lower outcomes will suggest the need for further refinement of the program

Table 1. Study design and data analysis plan details.

Variables	Description
First phase	
Woman's age	Date of birth, age categories
Husband's age	Date of birth, age categories
Baby's gender	Girl, Boy
Baby's age	Months
Woman's educational attainment	Years of education
Husband's educational attainment	Years of education
Woman's occupation	Employed, Housewife
Husband's occupation	Employed, Unemployed
Marriage duration	Months
Median household income	According to their monthly income
Mode of delivery	Normal vaginal delivery, Caesarean section
Fourth phase	
Participant's age	Date of birth, age categories
Husband's age	Date of birth, age categories
Gestational age	weeks
Participant's educational attainment	Years of education
Husband's educational attainment	Years of education
Participant's occupation	Employed, Housewife
Husband's occupation	Employed, Unemployed
Marriage duration	Months
Median household income	According to their monthly income
Intended mode of delivery	Normal vaginal delivery, Caesarean section

Table 2. Demographic and obstetric characteristics.

and your neighbours differ with you in postpartum?" (GRRs). It should be noted that the research questions will be arranged in a different sequence depending on the responses the participants provide to the previous question. Furthermore, some exploratory questions will also be asked during the interview, such as "What do you mean? Could you please explain why and how?". The interviewees will be asked at the end of their interviews, while thanking them for their participation in the study, about any non-addressed points to provide additional information if they are interested. Furthermore, the interviewer will be asked to contact them if any questions arise regarding their experiences to have another interview.

During the interview, the researcher will record non-verbal data including moods, body language, facial expressions, and posture of the participants. All interviews will be confirmed with the corresponding author who is the supervisor (M.J.) as well as advisors (Z.A., and F.ASh.). Following the completion of each interview, the recorded information is carefully listened to several times as soon as possible after the interview. Following on the coordination and permission of the participants, all interviews are recorded using a voice recorder and converted into audio files that are transferrable to the computer in order to concentrate more on the interview text and follow the data analysis method. The interviews are then transcribing word-by-word onto paper and coding is carried out. Initially, all coding processes will be done with the first author, and then they will be reviewed and approved by the supervisor and advisors of the study, who are also among the authors.

Trustworthiness and rigor

Qualitative findings will be evaluated according to five criteria: credibility, dependability, transferability, confirmability, and authenticity[44]. Credibility includes all activities that enhance the likelihood of obtaining valid data. This means that the results obtained reflect the meaning and intention of the participants. This criterion is intended to reflect the authenticity of the findings in accordance with the research objectives. In order to increase credibility in this research, methods such as continuous interaction with participants, random sampling, establishing intimate and trust-based relationships with participants, frequent meetings between the researcher and the project manager, member verifications and peer reviews, and integration will be applied. Dependability is achieved when the validity of the findings has been established by the researcher. The reliability and stability of findings over time and in the same conditions constitute dependability. It is similar to the concept of reliability in quantitative research. To gain a high degree of dependability, all participants will be asked the same questions in the same field, and all interviews will be recorded and documented verbatim. The concept of transferability is equivalent to that of external validity. For the study process to be transferable, the researcher attempts to provide detailed descriptions of the study process and makes it possible for others to follow the research process and actions taken throughout the study path in a clear, accurate, and purposeful manner (research context, participants, sampling method, time and location of data collection). Confirmability refers to the agreement between two or more independent individuals that the data is accurate, relevant, or meaningful. In order to increase the confirmability, in this research, the text of a number of interviews, codes and extracted classes will be available to colleagues and a number of faculty members who are familiar with the method of qualitative

research analysis, and they will be requested to verify the accuracy of the data coding process. Finally, to increase authenticity, which shows how honestly the researcher acted as a reporter in reporting events and facts in the study, the audio file and the extracted text of the interviews, as well as the extracted codes and classes, will be made available to the members of the research team for verification of the integrity of the process and reports[45].

Data analysis

A directed qualitative content analysis will be conducted using Kyngäs and Elo methods to analyse the data. There are three main phases to this analysis process, including preparation (open coding), organization (class development), and reporting (abstraction)[46]. Prior to open coding, written interviews are frequently analysed to obtain a general understanding of their content. The semantic units are extracted from the text during the open coding phase and the code is assigned to the semantic units using the MAXQDA software. Codes are compared and classified according to their relationships and differences during the class development phase. These codes will then be placed in subclasses and classes based on their relationships and differences. Additionally, during the abstraction phase, new classifications will be defined based on the codes and content of the subclasses.

Second phase: review of literature.

In order to gain access to knowledge relevant to the issue, an electronic resource search will be conducted by using the Narrative Review method. To access more information, library resources (reviewing reference, books and dissertations) will be searched. Several databases will be searched to identify related articles, including PubMed, ScienceDrect, Web of Science, Cochrane Library, Scopus, ProQuest, Ovid, Magiran, SID, MEDLINE ،Embase، CINAHL Google Scholar. For this phase, all studies published in English and Persian languages between 2000 and 2023, with a qualitative, quantitative, or mixed design, will be reviewed to determine which papers are relevant with contents including "pregnancy", "postpartum", "maternal postpartum quality of life", "Quality of life", "factors affecting postpartum quality of life", "nulliparous women", "educational program", "sense of coherence", "general resource resistances", and "salutogenesis theory".

Third phase: developing an educational program.

According to the findings of the qualitative study, and reviewing the relevant literatures the educational needs of primiparous women will be defined. Then the educational priority will be reviewed by the expert panel. Analyse, Design, Develop, Implement, and Evaluate (ADDIE) model will be used to design this program. This template is used to design the educational program for adults. ADDIE is an instructional design and training develop model that provides a series of iterative steps for creating effective instruction in five mentioned phases. In this model, in the analysis phase, the educational needs and objectives are thoroughly examined. During the design phase, the educational content, duration, and delivery methods are defined. In the development phase, the instructional materials are created based on the design plan. The implementation phase involves delivering the educational program to the target audience. Finally, in the evaluation phase, the quality of the program and the participants' performance are assessed to ensure the objectives have been achieved[47].

Experts panel

The panel of experts will be prioritized the educational needs based on their applicability, and an intervention program will then be designed and implement in the quantitative phase based on these prioritized educational needs. Based on the results from the first and second phases of the study, the NGT will be used to prioritize the educational needs based on the decision matrix. Using this matrix, each proposed priority will be assigned a score between 1 and 3 according to three criteria: cost, ease and time of implementation. The matrix will be discussed with a number of experts in the group during the first round of discussions. Upon identifying the highest priority educational requirements, the training program will be designed accordingly. Following the first round of evaluation, the proposed training program will be evaluated qualitatively by the panel members in the second round. In addition, these experts will be asked to provide their comments on the copied training program. Eventually, the designed training program will be finalized, and implemented in the fourth phase (quantitative study).

Fourth phase: Randomized controlled trial.

This phase will be reported based on the CONSORT 2010 checklist[48].

Study design, participants and setting

Nulliparous women referred to comprehensive health service centers affiliated with Ahvaz Jundishapur University of Medical Sciences will form the sample population. Nulliparous women, with a gestational age of 28 weeks and above, over 18 years old, singleton pregnancy, ultrasound confirmation of fetal health, and no history of depression or long-term medical illness in the past as indicated by the mother's statement, are eligible to include to the study. Infertile women, women who have been pregnant following assisted reproductive treatment, women who refuse to complete questionnaires, women who are unable to be reached for unexpected reasons, and women with a sick spouse will be excluded from the study.

Sample size

According to the study objective and based on the previous study results[26], and considering $\mu1 = 74.7$ and $\mu2 = 68.0$, and with $SD1 = 9.7$ and $SD2 = 9.9$, and using med calc statistical software with 90% power and 5% error, 92 cases were determined (46 cases in each group). Sample size for each group will be determined to be 55 by an attrition rate of 20%.

$$n = 2\frac{\left(z_{1-\alpha/2} + z_{1-\beta}\right)^2 + \left(SD_1^2 + SD_2^2\right)}{\left(\mu_1 - \mu_2\right)^2}$$

Sampling method

First, all healthcare centres in Ahvaz will be contacted to obtain a list of nulliparous women who meet the inclusion criteria. A brief explanation of the purpose and methodology of the research will be provided to the selected women through their contact information, and then they will be invited to participate in the study. Until the predetermined number of participants has been recruited, the sampling process will continue.

A random allocation method using blocked randomization with blocks of six will be employed to divide nulliparous women into two parallel groups for the intervention (ST-based training program along with routine childbirth preparation classes) and the control group (routine childbirth preparation classes). For allocation concealment, an individual with no knowledge of the research objectives will write the names of the control and intervention groups and place them in numbered identical closed and opaque envelopes. When selecting envelopes, an individual not involved in the study will be asked to do so. After obtaining informed consent and allocation concealment of participants in two groups, the intervention will be performed by the researcher (Table 1).

Data collection tools

The measurement tools of this study are a demographics questionnaire (Table 2), Antonovsky's SOC scale (SOC-13), the maternal self-efficacy questionnaire (MSQ), the maternal postpartum quality of life instrument (MPQOL-I), and the breastfeeding self-efficacy scale-short form (BSES-SF). It is notable that depending on the results obtained from the first phase of the study, there would be changes in the measurement tools.

There are 13 questions in SOC-13 that measure SOC, and it includes three subscales which measure comprehensibility (5 questions), manageability (4 questions), and meaningfulness (4 questions)[49]. Each item is scored according to a 7-point Likert scale, with a total score between 13 and 91. Low, moderate, and high levels of SOC are indicated by scores between 13_60, 61–75, and 76–91, respectively. Mohammadzadeh et al. confirmed the validity and reliability of this questionnaire in Iran. The reliability of the questionnaire was confirmed with Cronbach's alpha coefficient of 0.77 [50].

The MSQ was developed by Reece in 1992. It consists of 25 items rated on a 10-point Likert scale (from I cannot to definitely can), all of which are positive. The minimum and maximum scores of this questionnaire are 25 and 250, respectively, and a score below 25 indicates that the mother has a low level of self-efficacy and a score higher indicates that the mother has a high level of self-efficacy[51]. Jafarnejad et al. confirmed the validity and reliability of this questionnaire in Iran[52].

The MPQOL-I was developed by Mokhtaryan et al. in 2022 in Iran in order to measure postpartum QoL. The questionnaire contains 16 items on a five-point Likert scale (very much, much, moderately, little, very little/not at all). Scores range from 16 to 80. High scores indicate a high postpartum QoL. It has been confirmed that this questionnaire is valid and reliable in Iran[7].

The BSES was developed by Dennis and Faux in 1999 to assess breastfeeding confidence[53]. The scale consists of 33 items prefixed with the phrase "I can always" and scored on a 5-point Likert scale ranging from 1 (not at all confident) to 5 (always confident). So, total scores can range from 33 to 165, with higher scores indicating greater levels of breastfeeding self-efficacy. In 2003, Dennis revised the BSES from 33 to 14 items and renamed it the BSES-Short Form (BSES-SF). A similar theoretical framework is utilized as in the original version of BSES. The minimum and maximum score is 14 and 70 respectively[54]. The validity and reliability of this tool in Iran was confirmed by Amini et al. in 2019 [55].

Intervention

The intervention will consist of four weekly sessions, each lasting at least 30 min. In order to increase the effectiveness of the training program, appropriate audiovisual training methods and tools will be used. Noteworthy, based on the results of the first phase of the study, the number of sessions and their duration may be adjusted. Intervention sessions will be conducted in groups consisting of at least four nulliparous women. In spite of this, the size of the groups may vary depending on the conditions.

In the pre-test phase, after informed consent has been obtained from the participants, only the SOC-13 questionnaire will be completed. Training sessions will be led by Ph.D Student in midwifery. Then, the developed training content will be implemented. It is anticipated that these training sessions will utilize a variety of educational techniques, including lectures, group discussions, problem-solving, brainstorming, and sharing of feelings and ideas, as well as various educational tools relating to the relevant training domain, including books, brochures, photographs, and videos.

Participants in the control group will receive only routine childbirth preparation provided by health center staffs. In addition to this, intervention group participants will also engage in training program sessions based on ST. Participants will be notified of the times and locations of each training session by text message before it takes place. A telephone number will also be provided to participants in order to contact the researcher if they have any questions.

As a result of the nature of the study, blinding both participants and the researchers is not possible. Therefore, in order to prevent contamination, training sessions will be held for the intervention group on one of the three days at the beginning of the week. Following the study's participants, it will be evaluated in the postpartum period with the SOC-13, MSQ, MPQOL-I, and BSES-SF questionnaires to see if this intervention is effective on SOC, maternal self-efficacy, postpartum QoL, and breastfeeding self-efficacy. Following delivery, the same

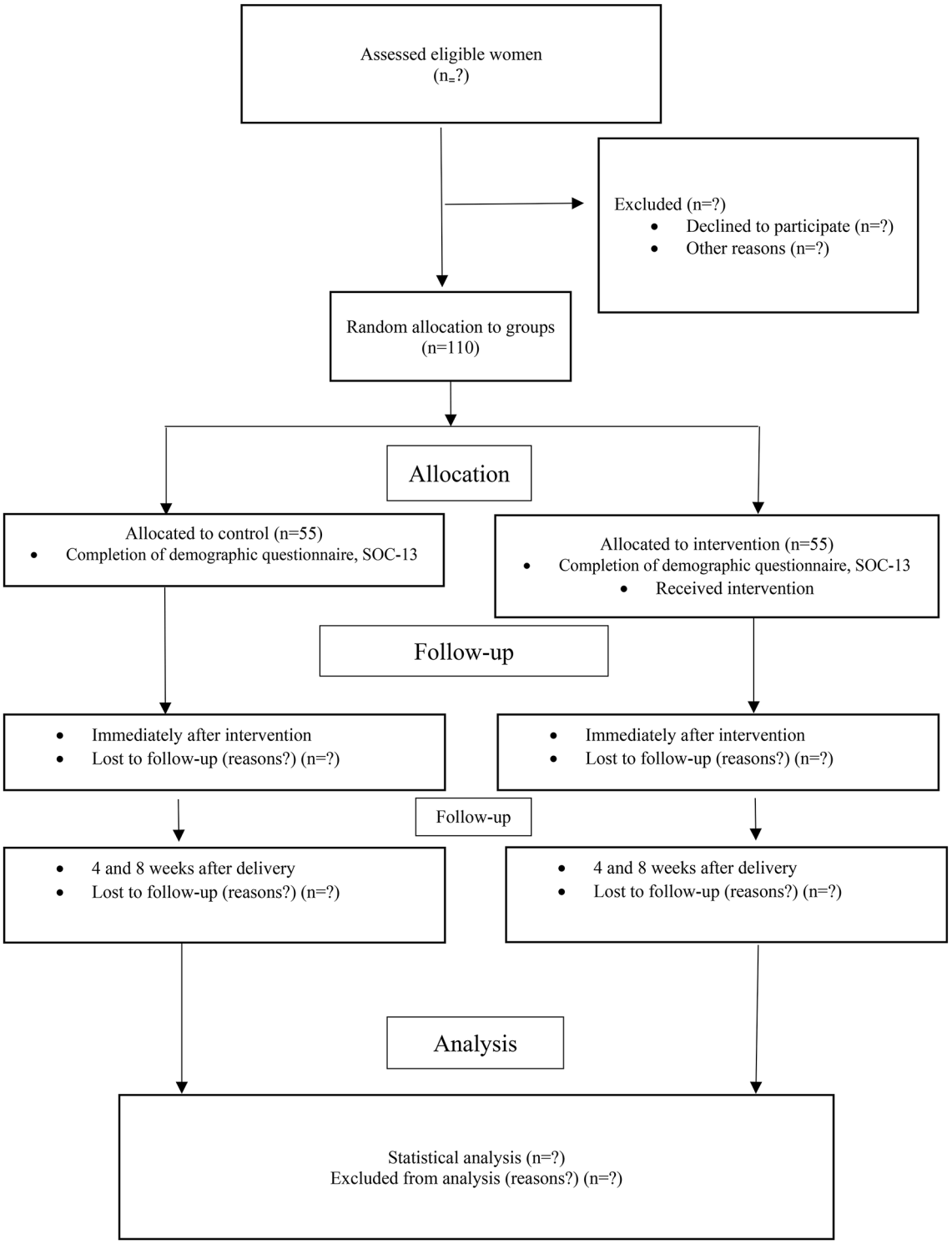

Fig. 2. CONSORT flow diagram of the study randomized controlled trial protocol.

questionnaires will be completed again four and eight weeks after delivery to monitor possible changes. The flow diagram of the study is shown in Fig. 2.

Statistical analysis

After checking the normal distribution of the data with the Kolmogorov-Smirnov test, the data are statistically analysed in SPSS software. Quantitative variables will be reported as mean, standard deviation, minimum and maximum, and qualitative variables will be reported as number (percentage). To check the relationship between qualitative variables, the chi-square test (or Fisher's exact test) and to compare quantitative variables

between two independent groups (intervention and control) and determine the effectiveness of the intervention, independent t-test or its non-parametric equivalent (U Mann-Whitney) will be used. Also, repeated measures, paired t-tests and analysis of variance (ANOVA) will be used according to the objectives of the study. If the data is not normally distributed, non-parametric tests will be used. Effect size will be calculated and reported. Data will be analysed on an (invitation to tender) ITT basis. The significance level for all tests will be considered less than 0.05 ($p < 0.05$).

Ethical considerations

The project aligns with the principles outlined in the Declaration of Helsinki (amended in 2013) and adheres to all relevant local ethical standards and was approved by the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences. Participants will be informed that they can withdraw from the study at any time. Additionally, they will be assured that their personal information will remain confidential and that the data will be analysed anonymously. A checklist of Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) has been used as the basis for writing this manuscript.

Limitation

It appears that the study protocol has few potential limitations. Firstly, due to the extended time between intervention and follow-up, high attrition may threaten the validity of the study. To secure the study from this limitation, the sample size was determined in light of this limitation as well as a contact number will be obtained from the participants in order to get in touch with them. Secondly, blinding participants to the group assignment will not possible due to the nature of the intervention. Once the intervention is being implemented, certain days of the week will be assigned to the participants in two groups as a means of preventing contamination.

Conclusions

Our study findings can be used to empower midwifery students and midwives to enhance the SOC of women, postpartum QoL, maternal self-efficacy, and maternal health, and to implement a new training program that will improve the effectiveness of childbirth preparation classes. In view of one of this study's objectives is comparing vaginal deliveries among two groups, if the results indicate that this program is effective at increasing the number of vaginal deliveries, then the program's practical strategies may be able to prevent unnecessary caesarean section.

Data availability

Data of this study will be available upon the request from the corresponding author.

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Author contributions

The study protocol was designed by M.Sh., M.J., Z.A., and F.ASh. M.J. will provide supervision throughout the study as a principal investigator. M.Sh. drafted the manuscript. M.J., Z.A., and F, ASh., contributed to the critical revision of the manuscript. M.Sh. will be responsible for participant recruitment, randomization, data collection and data management. M.Sh., M.J, Z.A., F.ASh., and S.Gh. will contribute to the data analysis of the project. All authors have read and approved the final manuscript.

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Competing interests
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Ethics approval and consent to participate
The project aligns with the principles outlined in the Declaration of Helsinki (amended in 2013) and adheres to all relevant local ethical standards and was approved by the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences (IR.AJUMS.REC.1402.137). It has been registered with the Iranian Registry of Clinical Trials (IRCT20230626058592N1).

Additional information
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