BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-069609
Article Type:	Protocol
Date Submitted by the Author:	28-Oct-2022
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Keywords:	Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH, HEALTH SERVICES ADMINISTRATION & MANAGEMENT, OBSTETRICS

Presentation of a modified physiologic birth program integrated into Iran's health system and its effect on maternal and neonatal outcomes: An embedded mixed method study protocol

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ABSTRACT

Introduction

According to the recommendation of the World Health Organization, the promotion of physiologic birth is a main strategy for reducing cesarean sessions and achieving the Sustainable Development Goals. This mixed method study will be conducted to provide a modified physiologic birth program which can be integrated into the health system.

Methods and analysis

This embedded mixed method study has a qualitative phased which will be conducted before the clinical trial. The first phase will be a qualitative study which will be conducted through semi-structured in-depth targeted interviews with the recipients and providers of the physiologic birth program services. Data analysis will be performed using the conventional content analysis approach. Then, for the design of the intervention, the national and international guidelines of physiologic birth will be reviewed, and the panel of experts will be utilized by using the Delphi method. The second phase, will be a randomized controlled trial that aim is to investigate the effect of the designed intervention of the physiologic birth program on maternal and neonatal outcomes and the childbirth experiences of mothers, and will be conducted on 252 eligible pregnant women in two intervention and control groups. Finally, the qualitative and quantitative phases will result in a physiologic birth program which can be integrated into the health system.

Ethics and dissemination

This study was approved by the Ethical Committee of Ahvaz Jundishapur University of Medical Sciences (IR.AJUMS.REC.1401.050). The findings of the study will be provided to the beneficiaries in appropriate ways. The program resulting from this study can help health planners and policy makers to implement high-quality physiologic birth program. Trial registration IRCT20220406054438N1

Strengths and limitations of this study

- Using a combination of quantitative and qualitative approach, compared to when each of these approaches is used separately, provides a better understanding of the research questions.
- The embedded mixed method of the qualitative phase before designing the intervention can provide comprehensive and effective results.
- A clinical trial will be conducted with a large sample size to prove the effectiveness of the intervention. Thus, when the program is presented to managers and policy makers, it will have more executive guarantee and can be integrated into the health system.
- The limitation of the study is that the implemented program, while can be integrated into Iran's health system, may not be generalized to other countries. However, it can be implemented in countries with similar health services or can be used in other countries after being adapted.

INTRODUCTION

In recent decades, the rate of caesarean section has increased significantly in the world from less than 7% in 1970 to more than 21% in 2018 and is predicted to increase to 28.5% by 2030.[1] According to the World Health Organization (WHO) statement, since 1985, the international health care community considered the ideal cesarean rate to be 10-15%. Based on this statement, caesarean section, as one of the most prevalent types of surgery in the world, is growing rapidly, especially in developing countries. In its latest report of WHO in 2018, the the caesarean rate was 45.5% in Iran.[2] This rate is even up to 60% and more in private hospitals.[3] The rate of maternal caesarean-related mortality is 4 to 5 times that of vaginal delivery.[4] The rate of mortality is 2.1, 5.9 and 18.2 per 100,000 live births in vaginal delivery, elective caesarean and emergency caesarean respectively. Moreover, caesarean complications have been reported to be 20-25% that is greater than those of vaginal delivery.[5] According to the announcement of the Iranian Ministry of Health in 2014, Iran ranked second in the rate of caesarean section (54%) in the world.[6]

The results of the studies regarding the evaluation of the physiologic birth program in Iran revealed that the process of the program's evaluation is acceptable. However, the evaluation of input, output and operational ground can be improved more. The program needs correction of deficiencies and gaining the extensive cooperation of the stakeholders.[7,8,9] Studies in Iran showed the need for effective clinical guidelines to strengthen the policies of the health system by expanding the culture of physiological childbirth in order to improve the quality.[10,11,12]

The unchanged vaginal delivery rate that is 57% based on Iran's health development program indicates that the physiologic birth program could not effectively reduce the number of caesarean sessions, increase the number of vaginal deliveries, based on predetermined objectives, even in public hospitals.[13,14,15] Therefore, the success of a plan, such as physiologic plan program, in the healthcare system needs to be investigated.[16] No mixed method study has been conducted in Iran with the aim of designing an intervention regarding the physiologic birth program. Therefore, we aimed to examine the current situation of physiologic birth plan in Iran through a qualitative study. Then design an effective physiologic birth plan and implement it and check its effect on maternal and neonatal outcomes and birth experiences of mothers using a mixed method study.

The specific objectives

1. Explain the experiences, obstacles and strategies of implementing physiologic birth program from the perspective of the service recipients and providers
2. Design an intervention based on the total findings of the qualitative phase of the interviews, the opinions of experts and a review of the implementation of the physiologic birth program
3. Determine the impact of physiologic birth new program intervention on maternal and neonatal outcomes
4. Determine the effect of physiologic birth program intervention on the experiences of mothers
5. Present a physiologic birth program which can be integrated into the health system

METHODS AND ANALYSIS

Study design

This sequential embedded mixed method study will be conducted with a qualitative phase before the clinical trial (qualitative-quantitative). In this study, the qualitative stage (content analysis) will be conducted first, and the information obtained from this phase will be used as the basis for the intervention in the quantitative stage (clinical trial). Finally, the results of the qualitative and quantitative stages will be combined in the discussion and interpretation stage (Fig1).

This is an embedded study includes a qualitative part that aim to explain the experiences of recipients and health providers of the physiologic birth program services in Iran. Thus, in order to design the intervention for the physiologic birth program, the international guidelines for physiologic birth will be reviewed and an expert panel will be held using the Delphi method. The quantitative part will be a clinical trial which will be conducted to compare the effect of the intervention designed based on the physiologic birth program on maternal and neonatal outcomes and childbirth experiences. Finally, the qualitative and quantitative phases will result in a physiologic birth program which can be integrated into the health system (Fig2).

Qualitative phase of the study

The qualitative study will be conducted using the conventional content analysis approach to gain in-depth experiences of the recipients and providers of health services of physiologic birth program.

Sample size and sampling method

In this qualitative research, purposive sampling method will be used to select the participants, and sampling will continue until data saturation is reached, that is, until no new information is revealed regarding the categories or the relationship between them. The research population consists of service recipients (i.e. women who gave birth around six weeks ago and have participated in childbirth preparation classes and experienced physiologic birth with an accompanying midwife) and service providers (i.e. instructors of childbirth preparation classes, midwives, gynecologists, doulas, and executive directors).

Data Collection

To collect qualitative data, in-depth and semi-structured individual interviews will be conducted after obtaining informed consent of the participants. The interviews will be conducted by the first author of the article, who is a PhD candidate in midwifery. The second to fifth authors are professors of qualitative studies. She has completed educational and research courses in qualitative studies and has had the experience of collaborating in qualitative studies as an interviewer. It will be done under the supervision of the research team. The location of the interviews will be chosen by the participants without any time limit. Before starting the interview, the researcher will try to communicate and create a friendly environment by introducing herself and talking to the participants and answering their questions. The researcher will explain the reasons and objectives of the study. The researcher has interest and work experience in the field of physiological childbirth. who will conduct the interview by leaving aside the previous thoughts and assumptions. Demographic and obstetrical information required for participants will be recorded.

The consent of the participants will be obtained for recording the interview, and if recording is not allowed, full notes will be taken. There are no fixed and predetermined questions in semi-structured interviews, and questions are formed based on the interview process. To start the interview, the following general and open questions will be asked from the service recipients and service providers respectively: Please talk about your childbirth experience; please talk about your experience with physiologic birth program. In the process of the interview, in-depth

and probing questions will be asked based on the type of answer to each question to find out the depth of the experience. These questions include what do you mean? Why? Explain more; could you please give an example so that I can understand what you mean? Non-verbal data such as the participants' moods and characteristics including tone of voice, facial expressions and their posture will be recorded by the researcher during the interview. The interview will continue until data saturation is reached.

Data analysis

Conventional content analysis will be used for data analysis. The process of data analysis will be performed according to the steps suggested by Graneheim and Lundman.[17] First, the researcher will transcribe the interview verbatim and perform data analysis at the earliest possible time after conducting the interview, which is generally a few hours after the end of the interview. Then, the whole text will be read several times to get a general understanding of the interview content. Each meaning unit will be first converted into condensed meaning units which are then coded. The codes will be classified as subcategories and categories based on comparing their similarities and differences. Finally, the content of the categories will be revealed by considering their hidden meaning. Data analysis will be performed using MAXQDA software (version 10). The four criteria of Lincoln and Guba [18] will be used to increase the trustworthiness of the data. The credibility of the data will be ensured through the continuous involvement of the researcher with the subject of the research and spending enough time for data collection. The content of the categories will also be reviewed by the participants and the authors to ensure the concordance of the categories with the statements of the participants. Dependability will be ensured using the opinions of external observers (two midwifery and reproductive health specialists) as well as code-recode method during the analysis. Transferability of the findings is obtained through a detailed description of the context, participants, environment and conditions. Finally, to ensure confirmability, the researcher will put aside her presuppositions and thoughts and use the opinions of two midwifery and reproductive health specialists to reach a consensus on the process of forming the subcategories and categories.

Review of the guidelines

In the second stage of the study, the international and national guidelines for the physiologic birth program will be searched and reviewed. In order to have access to guidelines, clinical guidelines databases such as the World Health Organization Guidelines (WHO), The National

Institute for Health and Care Excellence (NICE), Agency for Healthcare Research and Quality (AHRQ) will be searched. The search for finding the available guidelines will be performed for latest guidelines in English or Persian and in databases such as MEDLINE, Web of Science, Embase, Scopus, ProQuest, Google scholar, and Magiran (SID) using keywords [Mesh].

Panel of experts

In the next part of the study, a specialized panel with the experts of the physiologic birth program will be held by using the Delphi method in the following stages.

First stage: selection of the panel members

Using purposive sampling method, the experts will be selected from among people who have a history of providing childbirth-related clinical services and have the experience of physiologic birth program (national instructors of physiologic birth, executive directors, midwives with clinical experience of physiologic birth, and gynecologists). The objectives of the study will be explained to these experts by the researcher and they are invited to participate in the study.

Second stage: asking questions from the panel members

In this stage, the panel members are asked to answer/explain the following open questions/comments in written or oral form.

- Express your experiences of the physiologic birth plan
- What are the obstacles to the implementation of the physiologic birth program?
- What strategies do you suggest for better implementation of the physiologic birth program?

Third stage: summarizing

After collecting the answers of the participants in the second stage, duplicate answers will be removed and answers with similar concepts will be merged. Then, the final results of the opinions and suggestions of the expert panel regarding the implementation of the physiologic birth program will be prepared.

Intervention design

In the third part of the study, the sum of the findings of the qualitative phase of the interviews, a review of the guidelines for the implementation of the physiologic birth program, and the opinions of experts in the field of physiologic birth will result in the intervention design.

Accordingly, the research team will prepare a summary based on a list of strategies obtained from the results of this stage for the improvement of the physiologic birth program and send it to the experts for prioritizing the strategies (4th stage of Delphi). Finally, the research team will decide on how to implement the intervention based on the frequent priorities.

Quantitative phase of the study

This study will be a randomized controlled trial with the aim of investigating the effect of the designed intervention of physiologic birth program on maternal and neonatal outcomes and mothers' childbirth experiences.

Sample size and sampling method

Given the aim of the study, considering the possible increase of the total score of childbirth experience in the intervention group compared to the control group by 15% in previous studies [19], and considering the test power of 80%, β=0.2, α=0.05, s1=0.73, s2=0.271 and d=0.271, the sample size is calculated through the following formula to be 114 participants in each group. Considering the probable 10% drop in the samples, the sample size will be 126 participants in each group of intervention and control.

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 (s_1^2 + s_2^2)}{(\mathrm{d})^2} = \frac{(1.96 + 0.84)^2 (0.73^2 + 0.73^2)}{(0.271)^2} \approx 114$$

This phase will be designed as a randomized controlled clinical trial with two intervention and control groups to investigate the effect of physiologic birth program on maternal and neonatal outcomes in healthcare centers of Ahvaz city in Iran. After obtaining the permission and approval of the Ethics Committee of Ahvaz University of Medical Sciences and registering the study in Iran's clinical trial center, the researcher will conduct the research based on the designed intervention. To select the participants, first the list of pregnant women will be prepared based on their electronic health records.

For the allocation of the participants to the intervention group (designed intervention for the physiologic birth program) and the control group (routine approach for the physiologic birth program), permuted block randomization technique with a random block size of 4-6 (using the table related to random permutations) and 1:1 allocation ratio will be used. The randomization list will be prepared by a statistician. In order to conceal the allocation, the intervention used in this research is allocated based on the randomized list by an external researcher who is not aware of the research objectives according to the corresponding codes in sealed envelopes.

Until the onset of the intervention, neither the researcher nor the participant will know who will be placed in which group. Due to the nature of the study, blinding is not possible in this study, but the outcomes assessors will be blinded to the purpose of the study. The intervention will be implemented after obtaining the informed consent of the participants. The final complete content and details of the intervention will be designed in the study process and after reviewing the results of the qualitative phase of the study and reviewing the literature and the results of the panel of experts. The general process of intervention based on the principles of physiologic birth, including childbirth preparation courses during pregnancy for low-risk pregnant mothers, will start from the 20th week of pregnancy (based on the current national protocol) and continue until the process of labor and physiologic birth. In fact, pregnant women will be accompanied by midwives who have a certificate on passing 60-hour physiologic birth approved by the Ministry of Health from pregnancy to labor and childbirth. The childbirth will take place in Sina or Allameh Karami public hospitals that are public hospitals and the physiologic birth program is currently being implemented.

The control group will participate in 8 sessions of the existing childbirth preparation classes and no intervention will take place for them. Finally, the maternal and neonatal outcomes, including the severity of labor pain, the duration of the labor stages, the amount of used oxytocin, the perineum condition, postpartum bleeding, type of delivery, 1 and 5-minute Apgar scores, the duration of the mother's hospitalization, breastfeeding in the first postpartum hour, hospitalization of the newborn, and the experiences of mothers with childbirth will be compared in the two groups.

Inclusion criteria

Inclusion criteria will be willingness to participate in the study, low-risk pregnant women (from 20th week of pregnancy), singleton pregnancy, 18-35-year-old women, live and healthy fetus with cephalic presentation, and normal body mass index.

Exclusion criteria

Exclusion criteria include any medical or obstetric problem that puts women in a high-risk group in terms of pregnancy, and high-risk process of labor and childbirth that prohibits physiologic birth.

Scales and data collection

The data collection tools will include demographic and obstetric information questionnaires, labor and delivery status checklist based on the mother's maternity records, and childbirth

experience questionnaire. Demographic and obstetric questionnaire (age, education, occupation, status of pre-pregnancy counseling, intended and unintended pregnancy, last menstrual period (LMP), gestational age, birth date, and body mass index (BMI) will be completed by the researcher before the intervention. Labor and delivery checklist is including the maternal and neonatal outcomes (severity of labor pain, duration of labor stages, amount of oxytocin use, perineal condition, postpartum bleeding, type of delivery, 1 and 5-minute Apgar scores, the duration of the mother's hospitalization, breastfeeding in the first postpartum hour, and hospitalization of the newborn) will be completed by the someone that is not aware of the objective of the study after delivery.

The childbirth experience questionnaire was designed by Dencker et al. in 2010. This tool measures the birth experience of primiparous women. The questionnaire includes the following areas: personal capacity, professional support, perceived security and participation. The answers will be ranged from completely agree (score 1), to completely disagree (score 4). The questions that will be answered based on a visual scale are converted into vales ranging from 1 to 4. A higher score in this tool means a more positive experience of childbirth. The validity and reliability of this tool in the English, Spanish, Danish, Malaysian and Iranian population have been proven in the study of Ghanbari et al[19,20]. This tool will be completed by the mother after giving birth (immediately or up to a maximum of one month).

Data analysis

Quantitative variables will be reported as mean, standard deviation, whereas qualitative variables will be reported as number (percentage). The normality of quantitative variables will be checked using the Shapiro-Wilk test. Chi-square test will be used to check the relationship between qualitative variables, and independent t-test or its non-parametric equivalent to compare quantitative variables between the two independent groups. Regression models will be used for determining the effectiveness of the intervention according to the type of outcome and the possibility of the presence of confounding variables. The significance level for the above tests is considered to be smaller than 0.05. Data will be analyzed using Stata software version 12.

Presentation of the program

The program will be presented according to the principles of the public health program. The main stages of this planning include analysis of the current context, goal setting, identification of the selected strategies, identification of obstacles to the implementation of the program,

interdepartmental cooperation, program design, program implementation and evaluation. In the present research, the qualitative and Delphi phase will be conducted through analyzing, targeting and formulation of the selected strategy. The program will be designed and implemented through doing the quantitative phase. The researchers will specify SWOT, interdepartmental collaborations and evaluation of the program.

The integration of the program into Iran's health system

In order to integrate the proposed program into the health system of Iran, the format of the Ministry of Health, will be used which is entitled the form for the integration of health programs into the country's health system. This form includes program overview, objectives and strategies, implementation model, list of support and service processes, list of resources, duty description of different levels of the program integration into the health system, list of the program monitoring and the program evaluation indicators.

Patient and public involvement

The participants in the process of analyzing and interpreting the interviews will be invited to review the results. The first researcher will interact with the interviewees in sharing the results of the study and intervention design and getting their experiences and opinions. After completing the study, participants will be invited to share their birth experiences with pregnant women. Therefore, participants or the public will be involved in the design, implementation and dissemination of this study.

Validity and reliability of the mixed research

In this study, to measure the validity of the mixed research, the following actions will be done; choosing the right persons for data collection in the quantitative and qualitative part, choosing the right sample size for the quantitative and qualitative phases, selecting appropriate samples to participate in the qualitative phase, using the significant results of the quantitative phase in the qualitative phase with the aim of further explanation and gaining a deeper understanding, integration and interpretation of the results of the quantitative and qualitative phase with the aim of answering the mixed research question, and consensus of the research team members regarding the general objectives of the research, methods and results.

DISCUSSION

This mixed method study will be conducted for the first time in Iran to provide a physiologic birth intervention program which can be integrated into the health system. According to the concepts of the WHO, physiologic birth program is one of the main strategies of reducing the rate of cesarean and improving maternal and neonatal health.[21,22]. Based on the guidelines of the WHO for positive childbirth experiences, efficient programs are needed for the provision of services from pregnancy through labor and delivery to postpartum period.[23] However, the implementation of the physiologic birth program in Iran is such that childbirth preparation classes are held in some health centers, but physiologic birth without the intervention is not implemented in accordance with the orders of the WHO. The modified program resulting from this study can help health planners and policy makers to implement high-quality physiologic birth in accordance with global recommendations.

This study has several strengths. Using a combination of quantitative and qualitative approach, compared to when each of these approaches is used separately, provides a better understanding of the research questions.[24] The embedded design is a type of mixed approach in which one type of data set plays a supporting and necessary role for another type. Researchers use this approach when they have large research projects ahead.[25,26] Therefore, the embedded mixed method of the qualitative phase before designing the intervention can provide comprehensive and effective results. A comprehensive review of the existing situation will be conducted through qualitative interviews with health service providers at the managerial, executive and clinical levels of the physiologic birth program to identify barriers and effective strategies. Moreover, a qualitative interview with mothers who have experienced physiological childbirth and have had an accompanying midwife can reflect their positive and negative experiences of this program. Given the fact that there is no accompanying midwife and continuous midwifery care in Iran's healthcare system, the results of this study can be used effectively in providing standard obstetric services in public centers. A clinical trial will be conducted with a large sample size to prove the effectiveness of the intervention. Thus, when the program is presented to managers and policy makers, it will have more executive guarantee and can be integrated into the health system.

The limitation of the study is that the implemented program, while can be integrated into Iran's health system, may not be generalized to other countries. However, it can be implemented in countries with similar health services or can be used in other countries after being adapted.

ETHICS AND DISSEMINATION

This study was approved by the Ethical Committee of Ahvaz Jundishapur University of Medical Sciences (Ref. ID: IR.AJUMS.REC.1401.050). Oral and written informed consent from the participants will be taken .Respondents can withdraw from the study any time during the data collection process without any consequences. All information will be kept confidential, and results will be reported in aggregated form. The findings of the study will be provided to the beneficiaries in appropriate ways. Including academic articles, national and international conferences and presentation of results to policymakers and related scientific associations and formal and informal meetings with stakeholders and participants in the study will be presented at any place and time. Trial registration number IRCT20220406054438N1.

Authors' contributions

AM, PA, MI, SK, NA, EM, NS conceptualized the study. AM, PA, MI, SK, NA, EM, NS contributed to the design of the study. AM drafted the manuscript. PA revised the manuscript. The authors read and approved the final manuscript.

Funding

The study was funded by The Ahvaz Jundishapur University of Medical Sciences grant number RHPRC-0103.

Competing interests None declared.

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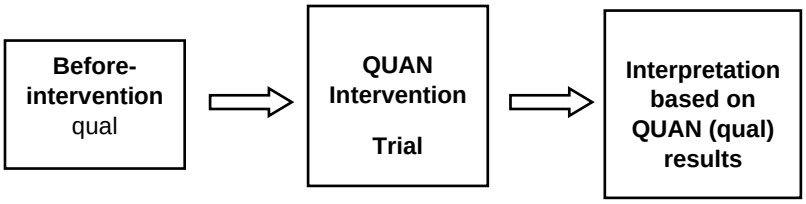

Fig. 1. Sequential an embedded mixed method design

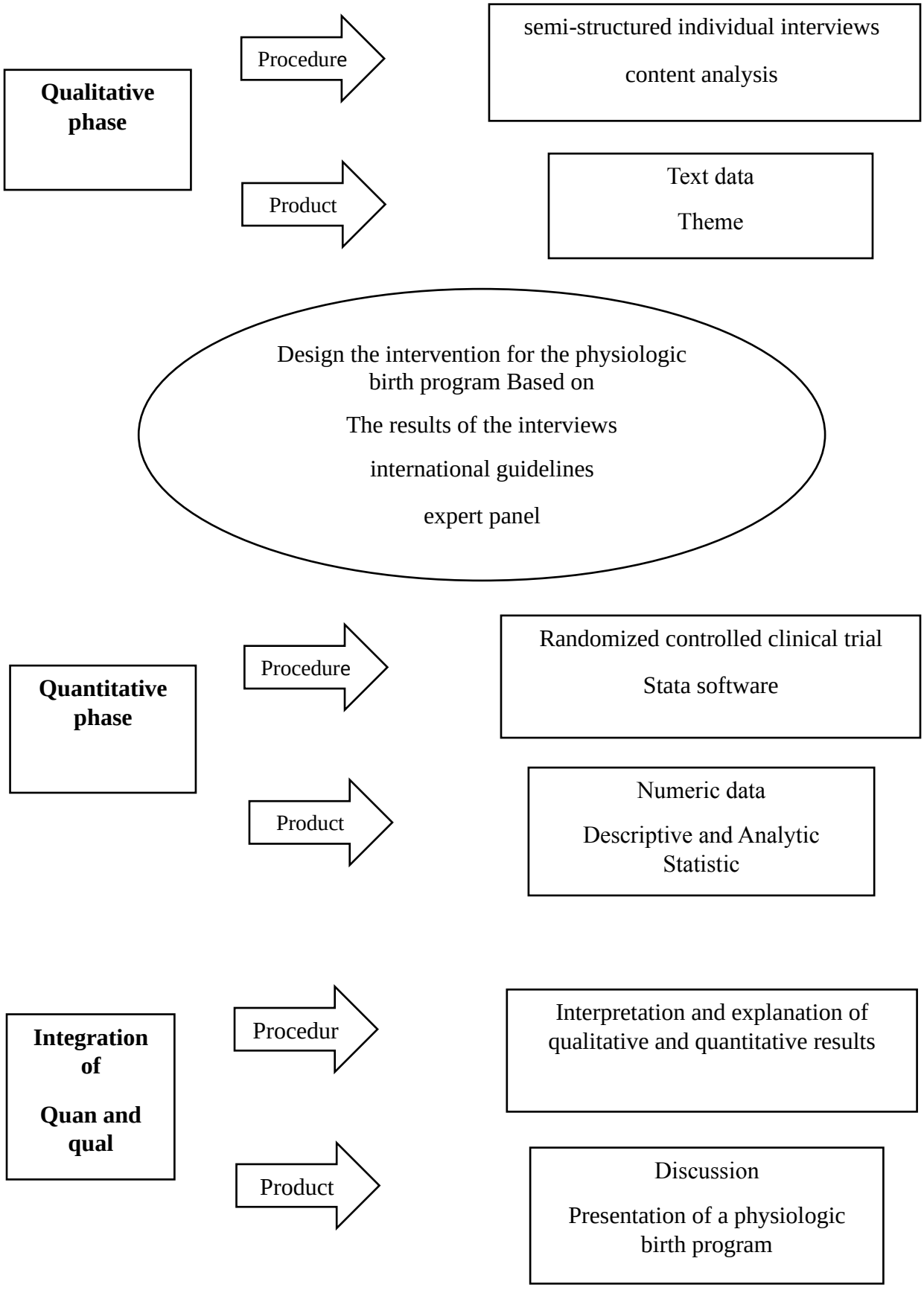

Fig.2 Study diagram

BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-069609.R1
Article Type:	Protocol
Date Submitted by the Author:	22-Feb-2023
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Primary Subject Heading:	Health policy
Secondary Subject Heading:	Global health, Health policy
Keywords:	Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH, HEALTH SERVICES ADMINISTRATION & MANAGEMENT, OBSTETRICS

Presentation of a modified physiologic birth program integrated into Iran's health system and its effect on maternal and neonatal outcomes: An embedded mixed method study protocol

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ABSTRACT

Introduction

According to the recommendation of the World Health Organization, the promotion of physiologic birth is a main strategy for reducing C-sections and achieving the Sustainable Development Goals. This mixed method study will be conducted to provide a modified physiologic birth program which can be integrated into the health system.

Methods and analysis

This embedded mixed method study has a qualitative phased which will be conducted before the clinical trial. The first phase will be a qualitative study which will be conducted through semi-structured in-depth targeted interviews with the recipients and providers of the physiologic birth program services. Data analysis will be performed using the conventional content analysis approach. Then, for the design of the intervention, the national and international guidelines of physiologic birth will be reviewed, and the panel of experts will be utilized by using the Delphi method. The second phase, will be a randomized controlled trial that aim is to investigate the effect of the designed intervention of the physiologic birth program on maternal and neonatal outcomes and the childbirth experiences of mothers, and will be conducted on 252 eligible pregnant women in two intervention and control groups. Finally, the qualitative and quantitative phases will result in a physiologic birth program which can be integrated into the health system.

Ethics and dissemination

This study was approved by the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences (IR.AJUMS.REC.1401.050). Informed consent was obtained from all participants. Findings from the study will be disseminated by publication of peer-reviewed manuscripts, presentations at scientific meetings and conferences with associated teams. This study was also registered in the Iranian Registry of Clinical Trials (IRCT20220406054438N1).

Strengths and limitations of this study

- A mixed-methods research design was adopted for a comprehensive review of the implementation of the physiologic birth program.
- A clinical trial was conducted with a large sample size to demonstrate the effectiveness of the intervention.
- The study was limited in that the implemented program may only be generalized to countries with similar health systems.

INTRODUCTION

In recent decades, the rate of caesarean section has increased significantly in the world from less than 7% in 1970 to more than 21% in 2018 and is predicted to increase to 28.5% by 2030.[1] According to the World Health Organization (WHO) statement, since 1985, the international health care community considered the ideal cesarean rate to be less than 10%. Notwithstanding, caesarean section, as one of the most prevalent types of surgery in the world, is growing rapidly. In the latest report of WHO in 2018, the caesarean rate in Iran was 45.5% [2] This rate is even up to 60% and higher in private hospitals.[3] The rate of maternal caesarean-related mortality is 4 to 5 times that of vaginal delivery.[4] The rate of mortality is 2.1, 5.9 and 18.2 per 100,000 live births in vaginal delivery, elective caesarean and emergency caesarean respectively. Moreover, caesarean complications have been reported to be 20-25% that is greater than those of vaginal delivery.[5] According to the announcement of the Iranian Ministry of Health in 2014, Iran ranked second in the rate of caesarean section (54%) in the world.[6]

The results of the studies regarding the evaluation of the physiologic birth program in Iran revealed that the process of the program's evaluation is acceptable. However, the evaluation of input, output, and operational grounds can be improved more. The program needs correction of deficiencies and attraction of the extensive cooperation of stakeholders. [7,8,9] Studies in Iran showed the need for effective clinical guidelines to strengthen the policies of the health system by expanding the culture of physiological childbirth in order to improve the quality.[10,11,12]

The unchanged vaginal delivery rate that is 57% based on Iran's health development program indicates that the physiologic birth program could not effectively reduce the number of caesarean sessions, increase the number of vaginal deliveries, based on predetermined objectives, even in public hospitals.[13,14,15] Therefore, the success of a plan, such as physiologic plan program, in the healthcare system needs to be investigated.[16] No mixed-methods study has been conducted in Iran with the aim of designing an intervention regarding the physiologic birth program. Therefore, we aimed to examine the current status of the physiologic birth plan in Iran through a qualitative study. Using a mixed method study, we intended to design and implement an effective physiologic birth plan and to check its effect on maternal and neonatal outcomes as well as birth experiences of mothers.

The specific objectives

1. Explain the experiences, obstacles and strategies of implementing physiologic birth program from the perspective of the service recipients and providers
2. Design an intervention based on the total findings of the qualitative phase of the interviews, the opinions of experts and a review of the implementation of the physiologic birth program
3. Determine the impact of physiologic birth new program intervention on maternal and neonatal outcomes
4. Determine the effect of physiologic birth program intervention on the experiences of mothers
5. Present a physiologic birth program which can be integrated into the health system

METHODS AND ANALYSIS

Study design

This sequential embedded mixed method study will be conducted with a qualitative phase before the clinical trial (qualitative-quantitative). In this study, the qualitative stage (content analysis) will be conducted first, and the information obtained from this phase will be used as the basis for the intervention in the quantitative stage (clinical trial). Finally, the results of the qualitative and quantitative stages will be combined in the discussion and interpretation stage (Fig1).

This is an embedded study includes a qualitative part that aim to explain the experiences of recipients and health providers of the physiologic birth program services in Iran. Thus, in order to design the intervention for the physiologic birth program, the international guidelines for physiologic birth will be reviewed and an expert panel will be held using the Delphi method. The quantitative part will be a clinical trial which will be conducted to compare the effect of the intervention designed based on the physiologic birth program on maternal and neonatal outcomes and childbirth experiences. Finally, the qualitative and quantitative phases will result in a physiologic birth program which can be integrated into the health system (Fig2).

Qualitative phase of the study

The qualitative study will be conducted using the conventional content analysis approach to gain in-depth experiences of the recipients and providers of health services of physiologic birth program.

Sample size and sampling method

In this qualitative research, purposive sampling method will be used to select the participants, and sampling will continue until data saturation is reached, that is, until no new information is revealed regarding the categories or the relationship between them. The research population consists of service recipients (i.e. women who gave birth around six weeks ago and have participated in childbirth preparation classes and experienced physiologic birth with an accompanying midwife) and service providers (i.e. instructors of childbirth preparation classes, midwives, gynecologists, doulas, and executive directors).

Data Collection

To collect qualitative data, in-depth and semi-structured individual interviews will be conducted after obtaining informed consent of the participants. The interviews will be conducted by the first author of the article, who is a PhD candidate in midwifery. The second to fifth authors are professors of qualitative studies. She has completed educational and research courses in qualitative studies and has had the experience of collaborating in qualitative studies as an interviewer. It will be done under the supervision of the research team. The location of the interviews will be chosen by the participants without any time limit. Before starting the interview, the researcher will try to communicate and create a friendly environment by introducing herself and talking to the participants and answering their questions. The researcher will explain the reasons and objectives of the study. The researcher has interest and work experience in the field of physiological childbirth. who will conduct the interview by leaving aside the previous thoughts and assumptions. Demographic and obstetrical information required for participants will be recorded.

The consent of the participants will be obtained for recording the interview, and if recording is not allowed, full notes will be taken. There are no fixed and predetermined questions in semi-structured interviews, and questions are formed based on the interview process. To start the interview, the following general and open questions will be asked from the service recipients and service providers respectively: Please talk about your childbirth experience; please talk about your experience with physiologic birth program. In the process of the interview, in-depth

and probing questions will be asked based on the type of answer to each question to find out the depth of the experience. These questions include what do you mean? Why? Explain more; could you please give an example so that I can understand what you mean? Non-verbal data such as the participants' moods and characteristics including tone of voice, facial expressions and their posture will be recorded by the researcher during the interview. The interview will continue until data saturation is reached.

Data analysis

Conventional content analysis will be used for data analysis. The process of data analysis will be performed according to the steps suggested by Graneheim and Lundman.[17] First, the researcher will transcribe the interview verbatim and perform data analysis at the earliest possible time after conducting the interview, which is generally a few hours after the end of the interview. Then, the whole text will be read several times to get a general understanding of the interview content. Each meaning unit will be first converted into condensed meaning units which are then coded. The codes will be classified as subcategories and categories based on comparing their similarities and differences. Finally, the content of the categories will be revealed by considering their hidden meaning. Data analysis will be performed using MAXQDA software (version 10). The four criteria of Lincoln and Guba [18] will be used to increase the trustworthiness of the data. The credibility of the data will be ensured through the continuous involvement of the researcher with the subject of the research and spending enough time for data collection. The content of the categories will also be reviewed by the participants and the authors to ensure the concordance of the categories with the statements of the participants. Dependability will be ensured using the opinions of external observers (two midwifery and reproductive health specialists) as well as code-recode method during the analysis. Transferability of the findings is obtained through a detailed description of the context, participants, environment and conditions. Finally, to ensure confirmability, the researcher will put aside her presuppositions and thoughts and use the opinions of two midwifery and reproductive health specialists to reach a consensus on the process of forming the subcategories and categories.

Review of the guidelines

In the second stage of the study, the international and national guidelines for the physiologic birth program will be searched and reviewed. In order to have access to guidelines, clinical guidelines databases such as the World Health Organization Guidelines (WHO), The National

Institute for Health and Care Excellence (NICE), Agency for Healthcare Research and Quality (AHRQ) will be searched. The search for finding the available guidelines will be performed for latest guidelines in English or Persian and in databases such as MEDLINE, Web of Science, Embase, Scopus, ProQuest, Google scholar, and Magiran (SID) using keywords [Mesh].

Panel of experts

In the next part of the study, a specialized panel with the experts of the physiologic birth program will be held by using the Delphi method in the following stages.

First stage: selection of the panel members

Using purposive sampling method, the experts will be selected from among people who have a history of providing childbirth-related clinical services and have the experience of physiologic birth program (national instructors of physiologic birth, executive directors, midwives with clinical experience of physiologic birth, and gynecologists). The objectives of the study will be explained to these experts by the researcher and they are invited to participate in the study.

Second stage: asking questions from the panel members

In this stage, the panel members are asked to answer/explain the following open questions/comments in written or oral form.

- Express your experiences of the physiologic birth plan
- What are the obstacles to the implementation of the physiologic birth program?
- What strategies do you suggest for better implementation of the physiologic birth program?

Third stage: summarizing

After collecting the answers of the participants in the second stage, duplicate answers will be removed and answers with similar concepts will be merged. Then, the final results of the opinions and suggestions of the expert panel regarding the implementation of the physiologic birth program will be prepared.

Intervention design

In the third part of the study, the sum of the findings of the qualitative phase of the interviews, a review of the guidelines for the implementation of the physiologic birth program, and the opinions of experts in the field of physiologic birth will result in the intervention design.

Accordingly, the research team will prepare a summary based on a list of strategies obtained from the results of this stage for the improvement of the physiologic birth program and send it to the experts for prioritizing the strategies (4th stage of Delphi). Finally, the research team will decide on how to implement the intervention based on the frequent priorities.

Quantitative phase of the study

This study will be a randomized controlled trial with the aim of investigating the effect of the designed intervention of physiologic birth program on maternal and neonatal outcomes and mothers' childbirth experiences.

Sample size and sampling method

Given the aim of the study, considering the possible increase of the total score of childbirth experience in the intervention group compared to the control group by 15% in previous studies [19], and considering the test power of 80%, β=0.2, α=0.05, s1=0.73, s2=0.271 and d=0.271, the sample size is calculated through the following formula to be 114 participants in each group. Considering the probable 10% drop in the samples, the sample size will be 126 participants in each group of intervention and control.

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 (s_1^2 + s_2^2)}{(\mathrm{d})^2} = \frac{(1.96 + 0.84)^2 (0.73^2 + 0.73^2)}{(0.271)^2} \approx 114$$

This phase will be designed as a randomized controlled clinical trial with two intervention and control groups to investigate the effect of physiologic birth program on maternal and neonatal outcomes in healthcare centers of Ahvaz city in Iran. After obtaining the permission and approval of the Ethics Committee of Ahvaz University of Medical Sciences and registering the study in Iran's clinical trial center, the researcher will conduct the research based on the designed intervention. To select the participants, first the list of pregnant women will be prepared based on their electronic health records.

For the allocation of the participants to the intervention group (designed intervention for the physiologic birth program) and the control group (routine approach for the physiologic birth program), permuted block randomization technique with a random block size of 4-6 (using the table related to random permutations) and 1:1 allocation ratio will be used. The randomization list will be prepared by a statistician. In order to conceal the allocation, the intervention used in this research is allocated based on the randomized list by an external researcher who is not aware of the research objectives according to the corresponding codes in sealed envelopes.

Until the onset of the intervention, neither the researcher nor the participant will know who will be placed in which group. Due to the nature of the study, blinding is not possible in this study, but the outcomes assessors will be blinded to the purpose of the study. The intervention will be implemented after obtaining the informed consent of the participants. The final complete content and details of the intervention will be designed in the study process and after reviewing the results of the qualitative phase of the study and reviewing the literature and the results of the panel of experts. The general process of intervention based on the principles of physiologic birth, including childbirth preparation courses during pregnancy for low-risk pregnant mothers, will start from the 20th week of pregnancy (based on the current national protocol) and continue until the process of labor and physiologic birth. In fact, pregnant women will be accompanied by midwives who have a certificate on passing 60-hour physiologic birth approved by the Ministry of Health from pregnancy to labor and childbirth. The childbirth will take place in Sina or Allameh Karami public hospitals that are public hospitals and the physiologic birth program is currently being implemented.

The control group will participate in 8 sessions of the existing childbirth preparation classes and no intervention will take place for them. Finally, the maternal and neonatal outcomes, including the severity of labor pain, the duration of the labor stages, the amount of used oxytocin, the perineum condition, postpartum bleeding, type of delivery, 1 and 5-minute Apgar scores, the duration of the mother's hospitalization, breastfeeding in the first postpartum hour, hospitalization of the newborn, and the experiences of mothers with childbirth will be compared in the two groups.

Inclusion criteria

Inclusion criteria will be willingness to participate in the study, low-risk pregnant women (from 20th week of pregnancy), singleton pregnancy, 18-35-year-old women, live and healthy fetus with cephalic presentation, and normal body mass index.

Exclusion criteria

Exclusion criteria include any medical or obstetric problem that puts women in a high-risk group in terms of pregnancy, and high-risk process of labor and childbirth that prohibits physiologic birth.

Scales and data collection

The data collection tools will include demographic and obstetric information questionnaires, labor and delivery status checklist based on the mother's maternity records, and childbirth

experience questionnaire. Demographic and obstetric questionnaire (age, education, occupation, status of pre-pregnancy counseling, intended and unintended pregnancy, last menstrual period (LMP), gestational age, birth date, and body mass index (BMI) will be completed by the researcher before the intervention. Labor and delivery checklist is including the maternal and neonatal outcomes (severity of labor pain, duration of labor stages, amount of oxytocin use, perineal condition, postpartum bleeding, type of delivery, 1 and 5-minute Apgar scores, the duration of the mother's hospitalization, breastfeeding in the first postpartum hour, and hospitalization of the newborn) will be completed by the someone that is not aware of the objective of the study after delivery.

The childbirth experience questionnaire was designed by Dencker et al. in 2010. This tool measures the birth experience of primiparous women. The questionnaire includes the following areas: personal capacity, professional support, perceived security and participation. The answers will be ranged from completely agree (score 1), to completely disagree (score 4). The questions that will be answered based on a visual scale are converted into vales ranging from 1 to 4. A higher score in this tool means a more positive experience of childbirth. The validity and reliability of this tool in the English, Spanish, Danish, Malaysian and Iranian population have been proven in the study of Ghanbari et al[19,20]. This tool will be completed by the mother after giving birth (immediately or up to a maximum of one month).

Data analysis

Quantitative variables will be reported as mean, standard deviation, whereas qualitative variables will be reported as number (percentage). The normality of quantitative variables will be checked using the Shapiro-Wilk test. Chi-square test will be used to check the relationship between qualitative variables, and independent t-test or its non-parametric equivalent to compare quantitative variables between the two independent groups. Regression models will be used for determining the effectiveness of the intervention according to the type of outcome and the possibility of the presence of confounding variables. The significance level for the above tests is considered to be smaller than 0.05. Data will be analyzed using Stata software version 12.

Presentation of the program

The program will be presented according to the principles of the public health program. The main stages of this planning include analysis of the current context, goal setting, identification of the selected strategies, identification of obstacles to the implementation of the program,

interdepartmental cooperation, program design, program implementation and evaluation. In the present research, the qualitative and Delphi phase will be conducted through analyzing, targeting and formulation of the selected strategy. The program will be designed and implemented through doing the quantitative phase. The researchers will specify SWOT, interdepartmental collaborations and evaluation of the program.

The integration of the program into Iran's health system

In order to integrate the proposed program into the health system of Iran, the format of the Ministry of Health, will be used which is entitled the form for the integration of health programs into the country's health system. This form includes program overview, objectives and strategies, implementation model, list of support and service processes, list of resources, duty description of different levels of the program integration into the health system, list of the program monitoring and the program evaluation indicators.

Patient and public involvement

The participants in the process of analyzing and interpreting the interviews will be invited to review the results. The first researcher will interact with the interviewees in sharing the results of the study and intervention design and getting their experiences and opinions. After completing the study, participants will be invited to share their birth experiences with pregnant women. Therefore, participants or the public will be involved in the design, implementation and dissemination of this study.

Validity and reliability of the mixed research

In this study, to measure the validity of the mixed research, the following actions will be done; choosing the right persons for data collection in the quantitative and qualitative part, choosing the right sample size for the quantitative and qualitative phases, selecting appropriate samples to participate in the qualitative phase, using the significant results of the quantitative phase in the qualitative phase with the aim of further explanation and gaining a deeper understanding, integration and interpretation of the results of the quantitative and qualitative phase with the aim of answering the mixed research question, and consensus of the research team members regarding the general objectives of the research, methods and results.

DISCUSSION

This mixed method study will be conducted for the first time in Iran to provide a physiologic birth intervention program which can be integrated into the health system. According to the concepts of the WHO, physiologic birth program is one of the main strategies of reducing the rate of cesarean and improving maternal and neonatal health.[21,22]. Based on the guidelines of the WHO for positive childbirth experiences, efficient programs are needed for the provision of services from pregnancy through labor and delivery to postpartum period.[23] However, the implementation of the physiologic birth program in Iran is such that childbirth preparation classes are held in some health centers, but physiologic birth without the intervention is not implemented in accordance with the orders of the WHO. The modified program resulting from this study can help health planners and policy makers to implement high-quality physiologic birth in accordance with global recommendations.

This study has several strengths. Using a combination of quantitative and qualitative approach, compared to when each of these approaches is used separately, provides a better understanding of the research questions.[24] The embedded design is a type of mixed approach in which one type of data set plays a supporting and necessary role for another type. Researchers use this approach when they have large research projects ahead.[25,26] Therefore, the embedded mixed method of the qualitative phase before designing the intervention can provide comprehensive and effective results. A comprehensive review of the existing situation will be conducted through qualitative interviews with health service providers at the managerial, executive and clinical levels of the physiologic birth program to identify barriers and effective strategies. Moreover, a qualitative interview with mothers who have experienced physiological childbirth and have had an accompanying midwife can reflect their positive and negative experiences of this program. Given the fact that there is no accompanying midwife and continuous midwifery care in Iran's healthcare system, the results of this study can be used effectively in providing standard obstetric services in public centers. A clinical trial will be conducted with a large sample size to prove the effectiveness of the intervention. Thus, when the program is presented to managers and policy makers, it will have more executive guarantee and can be integrated into the health system.

The limitation of the study is that the implemented program, while can be integrated into Iran's health system, may not be generalized to other countries. However, it can be implemented in countries with similar health services or can be used in other countries after being adapted.

ETHICS AND DISSEMINATION

This study was approved by the Ethical Committee of Ahvaz Jundishapur University of Medical Sciences (Ref. ID: IR.AJUMS.REC.1401.050). Oral and written informed consent from the participants will be taken .Respondents can withdraw from the study any time during the data collection process without any consequences. All information will be kept confidential, and results will be reported in aggregated form. The findings of the study will be provided to the beneficiaries in appropriate ways. Including academic articles, national and international conferences and presentation of results to policymakers and related scientific associations and formal and informal meetings with stakeholders and participants in the study will be presented at any place and time. Trial registration number IRCT20220406054438N1.

Authors' contributions

AM, PA, MI, SK, NA, EM, NS conceptualized the study. AM, PA, MI, SK, NA, EM, NS contributed to the design of the study. AM drafted the manuscript. PA revised the manuscript. The authors read and approved the final manuscript.

Funding

The study was funded by The Ahvaz Jundishapur University of Medical Sciences grant number RHPRC-0103.

Competing interests None declared.

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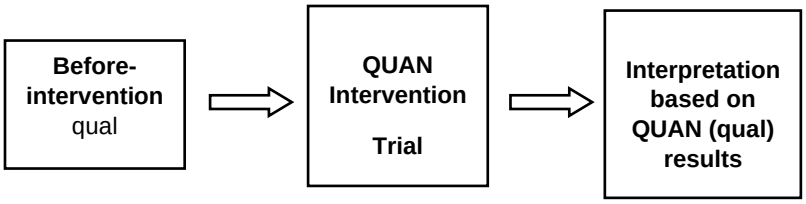

Fig. 1. Sequential an embedded mixed method design

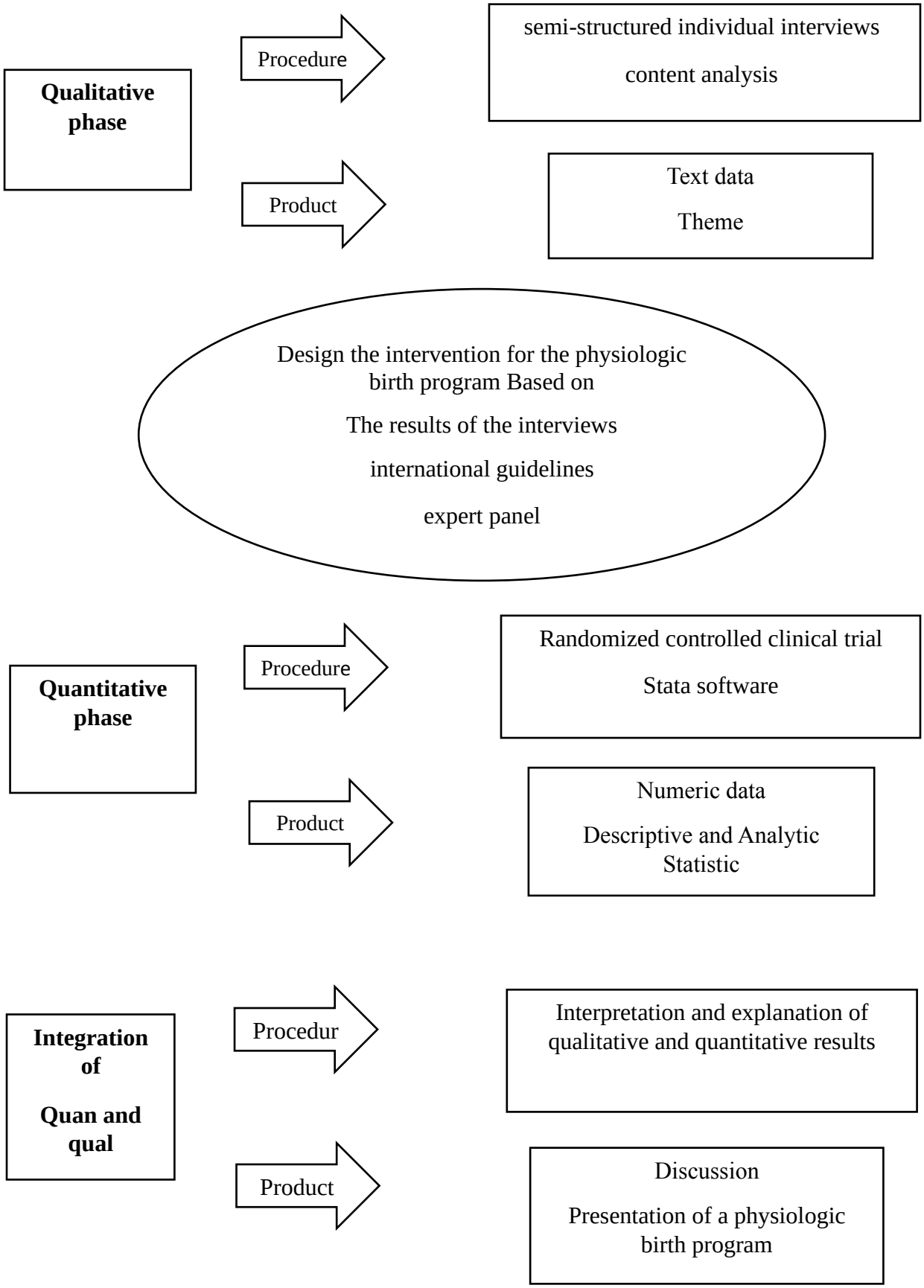

Fig.2 Study diagram

BMJ Open

Development of a modified physiologic birth program integrated into Iran's health system and its effect on maternal and neonatal outcomes: An embedded mixed-methods study protocol

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-069609.R2
Article Type:	Protocol
Date Submitted by the Author:	17-Apr-2023
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Primary Subject Heading:	Health policy
Secondary Subject Heading:	Global health, Health policy
Keywords:	Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH, HEALTH SERVICES ADMINISTRATION & MANAGEMENT, OBSTETRICS

Development of a modified physiologic birth program integrated into Iran's health system and its effect on maternal and neonatal outcomes: An embedded mixed-methods study protocol

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ABSTRACT

Introduction

As recommended by the World Health Organization, promotion of physiologic birth is a main strategy for reducing the rate of caesarean section and achieving the Sustainable Development Goals. This mixed-methods study was conducted to develop a modified physiologic birth program which can be integrated into the Iranian health system.

Methods and analysis

This embedded mixed-methods study had a qualitative phase which was conducted before a clinical trial. This qualitative phase was conducted through semi-structured in-depth targeted interviews with the recipients and providers of the physiologic birth program services. Data analysis was performed using conventional content analysis approach. Then, for the design of the intervention, national and international guidelines of physiologic birth were reviewed, and a panel of experts was convened using the Delphi method. The second phase of the study was a randomized controlled trial whose aim was to investigate the effect of the designed intervention of the physiologic birth program on maternal and neonatal outcomes and the childbirth experiences of mothers. It was conducted on 252 eligible pregnant women in two intervention and control groups. Finally, the results of the qualitative and quantitative phases contributed to the development of a physiologic birth program which can be integrated into the Iranian health system.

Ethics and dissemination

This study was approved by the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences (IR.AJUMS.REC.1401.050). Informed consent was obtained from all participants. Findings from the study will be disseminated by publication of peer-reviewed manuscripts, presentations at scientific meetings, and conferences with associated teams. This study was also registered in the Iranian Registry of Clinical Trials (IRCT20220406054438N1).

Strengths and limitations of this study

- A mixed-methods research design was adopted for a comprehensive review of the implementation of the physiologic birth program.
- A clinical trial was conducted with a large sample size to demonstrate the effectiveness of the intervention. The sample size was determined based on the review of the literature and considering the power of the study.
- The study was limited in that the modified program may only be generalized to countries with health systems similar to Iran's.

INTRODUCTION

In recent decades, the rate of caesarean section has increased significantly in the world from less than 7% in 1970 to more than 21% in 2018 and is predicted to rise to 28.5% by 2030.[1] According to the World Health Organization (WHO) statement, since 1985, the international health care community considered the ideal cesarean rate to be less than 10%. Notwithstanding, caesarean section, as one of the most prevalent types of surgery in the world, is growing rapidly. In the latest report of WHO in 2018, the caesarean rate in Iran was 45.5%. [2] This rate is even up to 60% and higher in private hospitals.[3] The rate of caesarean-related maternal mortality is 4 to 5 times that of vaginal delivery.[4] The rate of mortality in vaginal delivery, elective caesarean, and emergency caesarean is 2.1, 5.9 and 18.2 per 100,000 live births, respectively. Moreover, caesarean complications have been reported to be 20-25%, which is greater than the rate of those associated with vaginal delivery.[5] According to the announcement of the Iranian Ministry of Health in 2014, Iran ranked second in the rate of caesarean section (54%) in the world.[6]

The results of studies evaluating the physiologic birth program in Iran revealed that evaluation of the program in terms of process is acceptable. However, evaluation of input, output, and operational grounds shows the need for more improvement. The program needs to be corrected in terms of its deficiencies, and it should attract the extensive cooperation of stakeholders. [7,8,9] Studies in Iran have highlighted the need for effective clinical guidelines to strengthen the policies of the health system by promoting the culture of physiologic childbirth in order to improve its quality. [10,11,12]

However, the unchanged vaginal delivery rate, which is 57% based on Iran's health development program, indicates that the physiologic birth program could not effectively reduce the number of caesarean sessions and increase the number of vaginal deliveries based on predetermined objectives, even in public hospitals.[13,14,15] Therefore, it is imperative that the success of any program in the healthcare system should be carefully investigated, and the physiologic birth program is no exception.[16] In Iran, no mixed-methods study has yet been conducted to design an intervention regarding the physiologic birth program. Therefore, we aimed to examine the current status of the physiologic birth program in Iran through a qualitative study. Using a mixed-methods study, we intended to design and implement an effective physiologic birth program and to check its effect on maternal and neonatal outcomes as well as birth experiences of mothers.

The specific objectives

1. Explaining the experiences, obstacles, and strategies related to implementation of physiologic birth program from the perspective of the service recipients and providers
2. Designing an intervention based on the overall findings of the qualitative phase of the interviews, the opinions of experts, and a review of the implementation of the physiologic birth program
3. Determining the impact of the intervention based on the new physiologic birth program on maternal and neonatal outcomes
4. Determining the impact of the intervention based on the new physiologic birth program on the experiences of mothers
5. Developing a physiologic birth program which can be integrated into the health system

METHODS AND ANALYSIS

Study design

This sequential embedded mixed-methods study included a qualitative phase and a clinical trial (qualitative-quantitative). In this study, the qualitative phase (content analysis) was conducted first, and the information obtained from this phase was used as the basis for the intervention in the quantitative phase (clinical trial). Finally, the results of the qualitative and quantitative phases were merged in the discussion and interpretation stage (Fig1).

This is an embedded study including a qualitative phase aimed at explaining the experiences of recipients and providers of the physiologic birth program services in Iran. Thus, in order to design the intervention for the physiologic birth program, the international guidelines for physiologic birth were reviewed, and a panel of experts was convened using the Delphi method. The quantitative phase was a clinical trial which was conducted to compare the effect of the intervention based on the physiologic birth program on maternal and neonatal outcomes and childbirth experiences. Finally, the results of the qualitative and quantitative phases were used to develop a physiologic birth program which can be integrated into the Iranian health system (Fig2).

Qualitative phase of the study

This phase of study was conducted using the conventional content analysis approach to gain in-depth experiences of the recipients and providers of health services of physiologic birth program.

Sample size and sampling method

In this qualitative research, purposive sampling method was used to select the participants, and sampling continued until data saturation; that is, until no new information is revealed regarding the categories or the relationship between them. The selection of samples was based on the inclusion criteria with maximum diversity and generalizability. The research population consisted of service recipients (i.e. women who had given birth around six weeks prior to the commencement of the study and had participated in childbirth preparation classes and experienced physiologic birth with an accompanying midwife) and service providers (i.e. instructors of childbirth preparation classes, midwives, gynecologists, doulas, and executive directors).

Data Collection

To collect qualitative data, in-depth and semi-structured individual interviews were conducted after obtaining informed consent from the participants. The interviews were conducted by the first author of the article (AM), who is a PhD candidate in midwifery. The second to fifth authors are faculty members with notable experience and expertise in qualitative studies. At the time of doing the interviews, AM had already completed her theoretical and research courses on qualitative studies and had the experience of collaborating in a number of qualitative studies as an interviewer. Of course, all interviews were conducted under the supervision of the research team. The time and place of the interviews were chosen at the participants' consent without any restriction. Before starting the interview, the interviewer tried to establish a good relationship with the participants and create a friendly environment by introducing herself and talking to the interviewees and answering their questions. The researcher explained the reasons and objectives of the study. It should be noted that AM has a particular interest and equally notable work experience in the field of physiological childbirth, so she conducted the interviews by leaving aside the previous thoughts and assumptions. The participants' demographic and obstetric information were recorded.

The consent of the participants was obtained for recording the interviews, and if recording was not allowed, careful field notes were taken. There are often no fixed and predetermined questions in

semi-structured interviews, and questions are formed as the interview unfolds. To start the interview, the following general and open questions were asked from the service recipients and service providers, respectively: “Please talk about your childbirth experience”, and “Please talk about your experience with physiologic birth program? As the interview proceeded, in-depth and probing questions were asked based on the type of answer to each question in order to delve into their experiences. These questions included: “What do you mean?”, “Why?”, “Explain more”, and “Could you please give an example so that I can better understand what you mean?” Paralinguistic features such as the participants' moods and characteristics including tone of voice, facial expressions and their posture were recorded by the researcher during the interview. The interviews continued until data saturation.

Data analysis

Conventional content analysis was used for data analysis. The process of data analysis was performed according to the steps suggested by Graneheim and Lundman. [17] First, the interviews were transcribed verbatim, and data analysis was done at the earliest possible time after conducting the interview, which was usually a few hours after the end of the interview. Then, the whole text was read several times to get a general understanding of the interview content. Each meaning unit was first converted into condensed meaning units which were then coded. The codes were classified as subcategories and categories based on comparison of their similarities and differences. Finally, the content of the categories was revealed by considering their hidden meaning. Data analysis was performed using MAXQDA software (version 10). The four criteria of Lincoln and Guba [18] were used to increase the trustworthiness of the data. The credibility of the data was ensured through continuous involvement of the researcher with the subject of the research and spending sufficient time on data collection. The content of the categories was also reviewed by the participants and the authors to ensure the concordance of the categories with the statements of the participants. Dependability was ensured using the opinions of external observers (two midwifery and reproductive health specialists) as well as code-recode method during analysis. Transferability of the findings was obtained through a detailed description of the context, participants, environment, and conditions. Finally, to ensure confirmability, the interviewer put aside her presuppositions and thoughts and used the opinions of two midwifery and reproductive health specialists to reach a consensus on the process of forming the subcategories and categories.

Review of the guidelines

In the second stage of the study, the international and national guidelines for the physiologic birth program were searched and reviewed. In order to have access to these guidelines, clinical guideline databases such as the World Health Organization (WHO) Guidelines, The National Institute for Health and Care Excellence (NICE), Agency for Healthcare Research and Quality (AHRQ) were searched. The search for finding the available guidelines was performed for the latest guidelines in English or Persian and in databases such as MEDLINE, Web of Science, Embase, Scopus, ProQuest, Google scholar, and Magiran (SID) using keywords [Mesh].

Panel of experts

In the next step of the study, a specialized panel of experts in the physiologic birth program was formed using the Delphi method in the following stages.

First stage: Selection of panel members

Using purposive sampling method, we selected the experts from among people who had a history of providing childbirth-related clinical services and had the experience of physiologic birth program (national instructors of physiologic birth, executive directors, midwives with clinical experience of physiologic birth, and gynecologists). The objectives of the study were explained to these experts by the research team, and they were invited to participate in the study.

Second stage: Asking questions from the panel members

In this stage, the panel members were asked to answer/explain the following open questions/comments in written or oral form.

- Express your experiences of the physiologic birth plan
- What are the obstacles to the implementation of the physiologic birth program?
- What strategies do you suggest for the better implementation of the physiologic birth program?

Third stage: Summarizing

After the answers of the participants in the second stage were collected, duplicate answers were be removed, and answers with similar concepts were merged. Then, the final results of the opinions

and suggestions of the expert panel regarding the implementation of the physiologic birth program were obtained.

Intervention design

In the third step of the study, the summary of the findings of the qualitative phase of the interviews, a review of the guidelines for the implementation of the physiologic birth program, and the opinions of experts in the field of physiologic birth led to the formulation of the intervention design. Accordingly, the research team prepared a summary based on a list of strategies obtained from the results of this stage for the improvement of the physiologic birth program. This summary was sent to the experts for prioritizing the strategies (4th stage of Delphi). Finally, the research team decided on how to implement the intervention based on the most frequent priorities.

Quantitative phase of the study

This phase of the study was a randomized controlled trial with the aim of investigating the effect of the designed intervention of physiologic birth program on maternal and neonatal outcomes and mothers' childbirth experiences.

Sample size and sampling method

Given the aim of the study and the possible increase in the total score of childbirth experience in the intervention group compared to the control group by 15% in a previous study [19], and assuming the test power of 80%, β=0.2, α=0.05, s1=0.73, s2=0.271 and d=0.271, we calculated the sample size through the following formula to be 114 participants in each group. Considering the probable 10% drop in the samples, the sample size rose to 126 participants in each group of intervention and control.

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 (s_1^2 + s_2^2)}{(\mathrm{d})^2} = \frac{(1.96 + 0.84)^2 (0.73^2 + 0.73^2)}{(0.271)^2} \approx 114$$

This phase was a randomized controlled clinical trial with two intervention and control groups to investigate the effect of physiologic birth program on maternal and neonatal outcomes in healthcare centers of Ahvaz city in Iran. After obtaining the permission and approval of the Ethics Committee of Ahvaz University of Medical Sciences and registering the study in Iranian Registry for Clinical Trials, the researchers started the research based on the designed intervention. To select

the participants, a list of pregnant women was first prepared based on their electronic health records.

In order to allocate the participants to intervention group (modified approach to the physiologic birth program) and the control group (routine approach to the physiologic birth program), permuted block randomization technique with a random block size of 4-6 (using the table of random permutations) and an allocation ratio of 1:1 were used. The randomization list was prepared by a statistician. For the purpose of allocation concealment, group allocation was done based on a randomized list made by an external researcher who was not aware of the research objectives, and the corresponding codes were kept in sealed envelopes. Prior to commencement of the intervention, both the researchers and the participants were masked to group allocation. Due to the nature of the study, blinding was not possible, but the outcome assessors were blinded to the purpose of the study. The intervention started after obtaining informed consent from the participants. The final and complete content as well as the details of the intervention was designed in the study process and after reviewing the results of the qualitative phase of the study, reviewing the literature, and obtaining the results of the panel of experts. The general procedure of the intervention was based on the principles of physiologic birth. This included childbirth preparation courses during pregnancy for low-risk pregnant mothers, which started from the 20th week of pregnancy (based on the current national protocol in Iran) and continued until the process of labor and physiologic birth. In fact, pregnant women were accompanied by midwives who had a certificate on passing a 60-hour physiologic birth program approved by the Ministry of Health from pregnancy to labor and childbirth. The participants gave birth to their babies at Sina or Allameh Karami public hospitals where the physiologic birth program is currently being implemented.

The control group attended 8 sessions of childbirth preparation classes and received no intervention. Finally, the maternal and neonatal outcomes, including the severity of labor pain, the duration of labor stages, the amount of oxytocin used, the perineum condition, postpartum bleeding, type of delivery, 1- and 5-minute Apgar scores, the duration of the mother's hospitalization, breastfeeding in the first postpartum hour, hospitalization of the newborn, and the experiences of mothers with childbirth were compared in the two groups.

Inclusion criteria

Inclusion criteria were: willingness to participate in the study, having low-risk pregnancy (from 20th week of pregnancy), having singleton pregnancy, being aged 18-35-year-old, giving birth to a live and healthy fetus with cephalic presentation, and having a normal body mass index.

Exclusion criteria

Exclusion criteria were: any medical or obstetric problem that put women in a high-risk group in terms of pregnancy, and high-risk process of labor and childbirth that prohibited physiologic birth.

Scales and data collection

The data collection tools in this study included a demographic and obstetric information questionnaire, labor and delivery status checklist based on the mother's maternity records, and childbirth experience questionnaire. The demographic and obstetric questionnaire (age, education, occupation, status of pre-pregnancy counseling, intended and unintended pregnancy, last menstrual period (LMP), gestational age, birth date, and body mass index (BMI) was completed by the researcher before the intervention. The labor and delivery checklist included the maternal and neonatal outcomes (severity of labor pain, duration of labor stages, amount of oxytocin used, perineal condition, postpartum bleeding, type of delivery, 1- and 5-minute Apgar scores, the duration of the mother's hospitalization, breastfeeding in the first postpartum hour, and hospitalization of the newborn) was completed by a research assistant who was not aware of the objective of the study after delivery.

The childbirth experience questionnaire was developed by Dencker et al. in 2010. This tool measures the birth experience of primiparous women. It includes the following areas: personal capacity, professional support, perceived security, and participation. The answers ranged from completely agree (score 1) to completely disagree (score 4). The questions that were answered based on a visual scale were converted into values ranging from 1 to 4. A higher score in this tool means a more positive experience of childbirth. The validity and reliability of this tool have been confirmed in English, Spanish, Danish, and Malaysian populations. Also, in the Iranian population, they have been proven in the study by Ghanbari et al [19,20]. This tool was completed by the mother after giving birth (immediately or up to a maximum of one month).

Data analysis

Quantitative variables were reported as mean ± standard deviation, whereas qualitative variables were reported as number (percentage). The normality of quantitative variables was checked using the Shapiro-Wilk test. Chi-square test was used to check the relationship between qualitative variables, and independent t-test or its non-parametric equivalent was used to compare quantitative variables between the two independent groups. Regression models were used for determining the effectiveness of the intervention according to the type of outcome and the possibility of the presence of confounding variables. The significance level for the above tests was considered to be smaller than 0.05. Data were analyzed using Stata software version 12.

Presentation of the program

The program was presented according to the principles of the public health program. The main stages of this program include analysis of the current context, goal setting, identification of the selected strategies, identification of obstacles to the implementation of the program, interdepartmental cooperation, program design, program implementation, and program evaluation. In the present research, the qualitative and Delphi phases were conducted through analyzing, targeting, and formulating the selected strategies. The program was designed and implemented based on the quantitative phase. The researchers specified SWOT, interdepartmental collaborations, and evaluation of the program.

The integration of the program into the Iranian health system

In order to integrate the proposed program into the health system of Iran, the format of the Ministry of Health, was used. It is entitled as “The form for the integration of health programs into the country's health system”. This form includes program overview, objectives and strategies, implementation model, list of support and service processes, list of resources, duty description of different levels of the program to be integrated into the health system, list of the program monitoring, and the program evaluation indicators.

Patient and public involvement

During the process of analyzing and interpreting the interviews, the participants were invited to review the results. The first author shared the results of the study and intervention design with the interviewees in and inquired about their experiences and opinions. After the study was completed,

participants were invited to share their birth experiences with pregnant women. Therefore, the participants or the public were involved in the design, implementation and dissemination of this study.

Validity and reliability of the mixed research

In this study, in order to ensure the validity of the mixed research, the following measures were taken: choosing the right persons for data collection in the quantitative and qualitative phases, choosing the right sample size for the quantitative and qualitative phases, selecting suitable participants for the qualitative phase, using the significant results of the quantitative phase in the qualitative phase with the aim of providing further explanation and gaining a deeper understanding, integration and interpretation of the results of the quantitative and qualitative phases with the aim of answering the mixed research question, and consensus of the research team members on the general objectives of the research, methods, and results.

DISCUSSION

This mixed method study was conducted for the first time in Iran to provide a physiologic birth intervention program which can be integrated into the health system. According to the recommendations of the WHO, the physiologic birth program is one of the main strategies for reducing the rate of cesarean section and improving maternal and neonatal health [21,22]. Based on the guidelines of the WHO for positive childbirth experiences, efficient programs are needed for the provision of services from pregnancy, labor, and delivery to postpartum period.[23] However, implementation of the physiologic birth program in Iran simply involves childbirth preparation classes held in designated health centers. This runs counter to WHO's recommendation that physiologic birth without intervention is not indeed implemented. The modified program developed in this study can help health planners and policy makers to implement high-quality physiologic birth programs in accordance with global recommendations.

This study has several strengths. Using a combination of quantitative and qualitative approaches, as opposed to when each is used separately, provides a better understanding of the research questions.[24] The embedded design is a type of mixed approach in which one type of data set plays a supporting and necessary role for another type. Researchers use this approach when they have large research projects ahead. [25,26] Therefore, the embedded mixed method of the qualitative phase before designing the intervention can provide comprehensive and effective

results. A comprehensive review of the existing status of physiologic birth program was done through qualitative interviews with health service providers at managerial, executive and clinical levels in order to identify barriers and devise effective strategies. Moreover, a qualitative interview with mothers who have experienced physiologic childbirth and have had an accompanying midwife can reflect their positive and negative experiences of this program. Given the fact that there is no accompanying midwife and continuous midwifery care in Iran's healthcare system, the results of this study can be used effectively in providing standard obstetric services in public centers. The clinical trial conducted in this study involved a large sample size to prove the effectiveness of the intervention. Thus, when the program is proposed to managers and policy makers, it will be more likely to be implemented and integrated into the health system.

The limitation of the study is that while the developed program in this study can be integrated into Iran's health system, it may not be generalized to other countries. Still, it can be implemented in countries with similar health services or can be used in other countries after applying the necessary modifications.

ETHICS AND DISSEMINATION

This study was approved by the Ethics Committee of Ahvaz Jundishapur University of Medical Sciences (Ref. ID: IR.AJUMS.REC.1401.050). Oral and written informed consent was obtained from the participants who were ensured that they could withdraw from the study any time during the data collection process without any consequences. They were also ensured that all information would be kept confidential and the results would be reported in aggregated form. The findings of the study were supposed to be provided to the beneficiaries in appropriate ways. These include academic articles as well as national and international conferences. The findings could also be presented to policymakers, related scientific associations, stakeholders or participants through formal or informal meetings at any time or place requested. Trial registration number IRCT20220406054438N1.

Authors' contributions

AM, PA, MI, SK, NA, EM, NS conceptualized the study. AM, PA, MI, SK, NA, EM, NS contributed to the design of the study. AM drafted the manuscript. PA revised the manuscript. The authors read and approved the final manuscript.

Funding

The study was funded by Ahvaz Jundishapur University of Medical Sciences (grant number RHPRC-0103).

Competing interests

None declared.

Fig. 1. Sequential an embedded mixed method design

Fig.2 Study diagram

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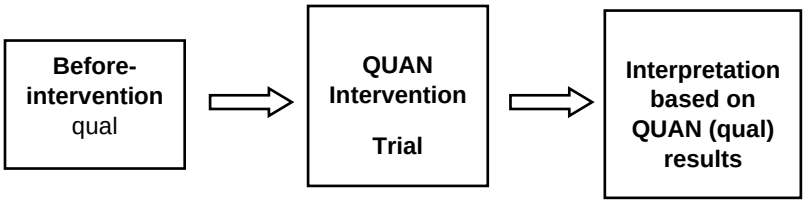

Fig. 1. Sequential an embedded mixed method design

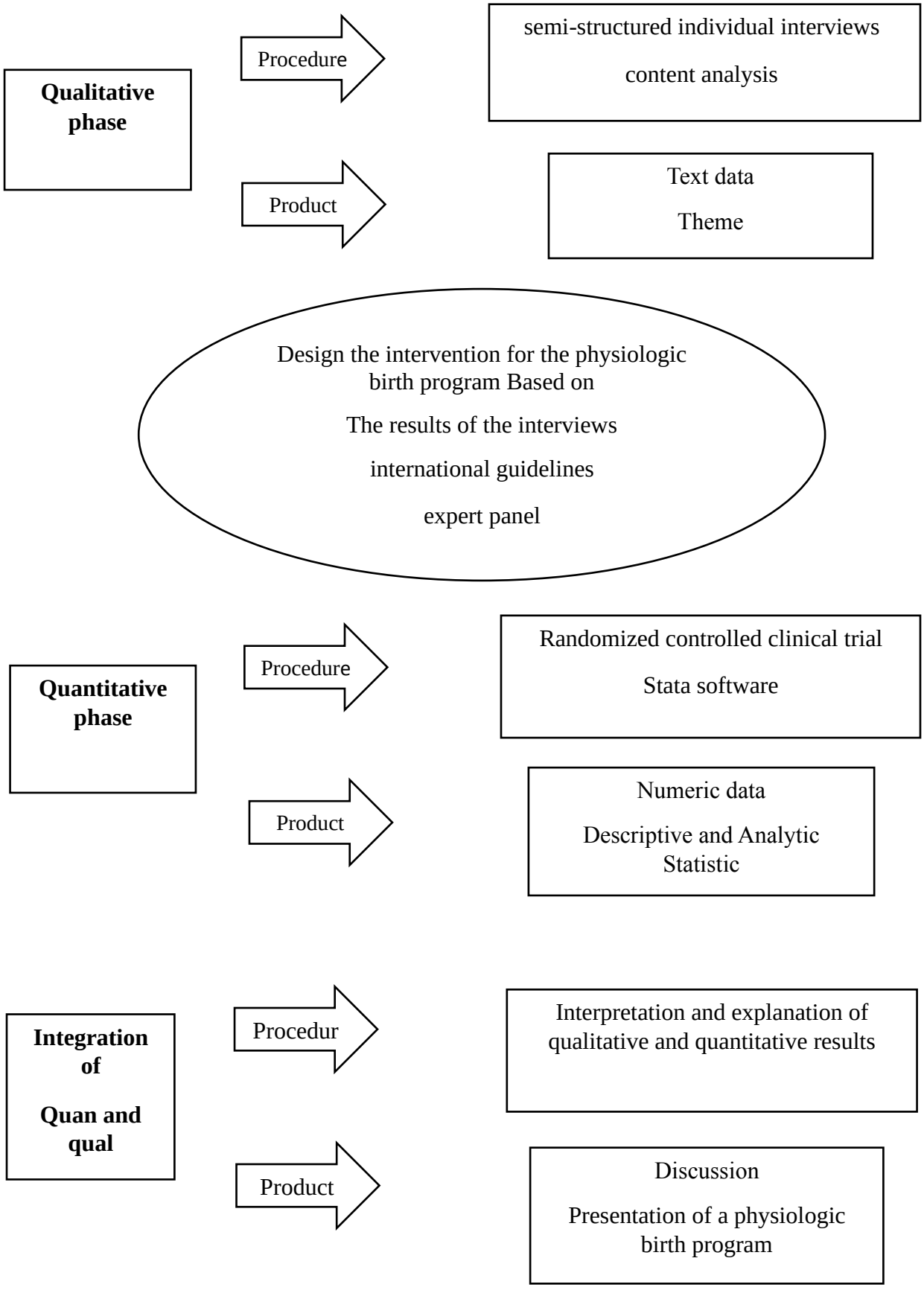

Fig.2 Study diagram

BMJ Open

Development of a Modified Physiologic Birth Program Integrated into Iran's Health System and its Effect on Maternal and Neonatal Outcomes: An Embedded Mixed-methods Study Protocol

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-069609.R3
Article Type:	Protocol
Date Submitted by the Author:	01-May-2023
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Primary Subject Heading:	Health policy
Secondary Subject Heading:	Global health, Health policy
Keywords:	Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, PUBLIC HEALTH, HEALTH SERVICES ADMINISTRATION & MANAGEMENT, OBSTETRICS

Development of a Modified Physiologic Birth Program Integrated into Iran's Health System and its Effect on Maternal and Neonatal Outcomes: An Embedded Mixed-methods Study Protocol

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ABSTRACT

Introduction

As recommended by World Health Organization, promotion of physiologic birth is a main strategy to reduce the rate of caesarean section, and achieving Sustainable Development Goals. A modified version of the physiologic birth program that may be included into the Iranian healthcare system was developed as a result of this mixed-methods research.

Methods and analysis

This embedded mixed-methods study had a qualitative phase that was conducted before a clinical trial. This qualitative phase was conducted via semi-structured in-depth targeted interviews with the recipients, and the providers of physiologic birth program services. Data analysis was performed using conventional content analysis approach. Then, for designing the intervention, national, and international guidelines of physiologic birth were reviewed, and a panel of experts was convened using Delphi method. A randomized controlled trial was used in the second phase of the research to examine the impact of the physiologic birth program's intended intervention on maternal and neonatal outcomes as well as mothers' experiences during labor. It was conducted on 252 eligible pregnant women in two intervention and control groups. Finally, the results of qualitative and quantitative phases contributed to developing a physiologic birth program which can be integrated into the Iranian health system.

Ethics Approval

This study was approved by Ethics Committee of Ahvaz Jundishapur University of Medical Sciences (IR.AJUMS.REC.1401.050). All participants gave their informed permission. The study's findings will be shared via the publishing of peer-reviewed articles, talks at scientific conferences, and meetings with related teams. This study was registered in the Iranian Registry of Clinical Trials (IRCT20220406054438N1).

Strengths and limitations of this study

- A mixed-methods research design for a comprehensive review of the implementation of physiologic birth program.
- A clinical trial with a large sample size to show the effectiveness of intervention.
- The limitation of the study is to generalize the modified program only to countries with a similar health system to Iran

INTRODUCTION

In recent decades, the rate of caesarean section has significantly increased in the world from less than 7% in 1970 to more than 21% in 2018 and is predicted to rise to 28.5% by 2030.[1] Based on World Health Organization (WHO) statement, since 1985, international health care community considered ideal cesarean rate to be less than 10%. Despite this, the number of caesarean sections, one of the most common surgical procedures worldwide, is rising quickly. The caesarean rate in Iran was 45.5 percent according to the most recent WHO data from 2018. [2] In private hospitals, this rate can reach as high as 60%. [3] The rate of caesarean-related maternal mortality is 4 to 5 times that of vaginal delivery.[4] The rate of mortality in vaginal delivery, elective caesarean, and emergency caesarean is 2.1, 5.9 and 18.2 per 100,000 live births, respectively. Moreover, the caesarean complications were reported to be 20-25%, which is greater than the rate of those associated with vaginal delivery.[5] Based on the announcement of the Iranian Ministry of Health in 2014, Iran ranked second in the rate of caesarean section (54%) in the world.[6]

The results of studies evaluating the physiologic birth program in Iran revealed that evaluating the program in terms of process is acceptable. However, analysis of the input, output, and operational factors reveals that there is still room for improvement. The program has to be improved in order to address its flaws, and a wide range of stakeholders should work together to make this happen. [7,8,9] Studies in Iran have highlighted the need for effective clinical guidelines to strengthen the policies of health system by promoting the culture of physiologic childbirth in order to improve its quality. [10,11,12]

However, unchanged vaginal delivery rate, which is 57% based on Iran's health development program, indicates that the physiologic birth program could not effectively reduce the number of caesarean sessions, and increase the number of vaginal deliveries based on predetermined objectives, even in public hospitals.[13,14,15] Therefore, it is imperative that the success of any program in the healthcare system should be carefully studied, and the physiologic birth program is no exception.[16] A mixed-methods research to provide an intervention for the physiologic birth program has not yet been carried out in Iran. We thus sought to conduct a qualitative research to investigate the present state of the physiologic birth program in Iran. Using a mixed-methods study, we intended to design, and implement an effective physiologic birth program and to check its effect on maternal and neonatal outcomes as well as birth experiences of mothers.

The specific objectives

1. Explaining experiences, obstacles, and strategies related to the implementation of physiologic birth program from the perspective of service recipients and providers
2. Designing an intervention based on the overall findings of the qualitative phase of interviews, the opinions of experts, and a review of the implementation of the physiologic birth program
3. Determining the effect of the intervention based on new physiologic birth program on maternal and neonatal outcomes
4. Determining the effect of the intervention based on new physiologic birth program on the experiences of mothers
5. Developing a physiologic birth program which can be integrated into the health system

METHODS AND ANALYSIS

Study design

This sequential embedded mixed-methods study included a qualitative phase, and a clinical trial (qualitative-quantitative). The qualitative phase (content analysis) of this research was carried out first, and the data from this phase served as the foundation for the intervention in the quantitative phase (clinical trial). Finally, the results of qualitative and quantitative phases were merged in the discussion and interpretation stage (Fig1).

This is an embedded study, including a qualitative phase aimed at explaining the experiences of recipients and providers of physiologic birth program services in Iran. Thus, to design the intervention for physiologic birth program, the international guidelines for physiologic birth were reviewed, and a panel of experts was convened using Delphi method. In order to assess the impact of the intervention based on the physiologic birth program on mother and neonatal outcomes as well as delivery experiences, a clinical trial was undertaken as part of the quantitative phase. Finally, the results of qualitative and quantitative phases were used to develop a physiologic birth program which can be integrated into the Iranian health system (Fig2).

Qualitative phase of the study

This phase of study was conducted using conventional content analysis approach to gain in-depth experiences of the recipients, and providers of health services of physiologic birth program.

Sample size and sampling method

Purposive sampling was employed to choose the participants in this qualitative study, and sampling continued until data saturation, or until no new information could be gleaned about the categories or how they related to one another. The inclusion criteria with the greatest possible variety and generalizability were used to choose the samples. The research population consisted of service recipients (i.e. women who had given birth around six weeks prior to the commencement of study, and had participated in childbirth preparation classes and experienced physiologic birth with an accompanying midwife) and service providers (i.e. instructors of childbirth preparation classes, midwives, gynecologists, doulas, and executive directors).

Data Collection

To collect qualitative data, in-depth and semi-structured individual interviews were conducted after obtaining informed consent from the participants. The interviews were conducted by the first author of article (AM), who is a PhD candidate in midwifery. The second to fifth authors are faculty members with notable experience and expertise in qualitative studies. AM had already finished her theoretical and research courses in qualitative studies at the time of the interviews, and she had experience working as an interviewer in a number of qualitative studies. Naturally, the research team served as the conductors of all interviews. The time and place of interviews were chosen at the participants' consent without any restriction. Before starting the interview, the interviewer tried to establish a good relationship with the participants, and create a friendly environment by introducing herself and talking to the interviewees, and answering their questions. The researcher explained the reasons and objectives of the study. AM has a particular interest and equally notable work experience in the field of physiological childbirth, so she conducted the interviews by leaving aside previous thoughts, and assumptions. The participants' demographic and obstetric information were recorded.

In order to record the interviews, participants had to provide their permission. If recording was not permitted, meticulous field notes were collected instead. In semi-structured interviews, questions

are often created as the interview progresses rather than being set and predefined. To start the interview, the following general and open questions were asked from the service recipients and service providers, respectively: “Please talk about your childbirth experience”, and “Please talk about your experience with physiologic birth program? As the interview proceeded, in-depth and probing questions were asked based on the type of answer to each question to delve into their experiences. These questions included: “What do you mean?”, “Why?”, “Explain more”, and “Could you please give an example so that I can better understand what you mean?” Paralinguistic features, such as the participants' moods and characteristics including tone of voice, facial expressions, and their posture were recorded by the researcher during the interview. The interviews continued until data saturation.

Data analysis

Conventional content analysis was used for data analysis. The process of data analysis was performed based on the steps suggested by Graneheim and Lundman. [17] First, the interviews were transcribed verbatim, and data analysis was done at the earliest possible time after conducting the interview, which was usually a few hours after the end of the interview. A broad idea of the interview's substance was then obtained by reading the whole text numerous times. Condensed meaning units of each meaning unit were created first, after which they were coded. Based on comparisons of their similarities and differences, the codes were divided into subcategories and categories. Finally, the content of categories was revealed by considering their hidden meaning. Data analysis was performed using MAXQDA software (version 10). The four criteria of Lincoln and Guba [18] were used to increase the trustworthiness of the data. The credibility of data was ensured via continuous involvement of the researcher with the subject of research, and spending sufficient time on data collection. The content of the categories was also reviewed by the participants and the authors to ensure the concordance of categories with the statements of participants. During analysis, dependability was ensured by relying on the insights of outside observers (two midwifery and reproductive health specialists). Through a thorough description of the context, participants, environment, and conditions, transferability of the findings was achieved. Finally, to ensure confirmability, the interviewer put aside her presuppositions and thoughts and used the opinions of two midwifery and reproductive health specialists to reach a consensus on the process of forming the subcategories and categories.

Review of the guidelines

In the second stage of the study, the international and national guidelines for the physiologic birth program were searched and reviewed. In order to having access to these guidelines, clinical guideline databases, such as World Health Organization (WHO) Guidelines, The National Institute for Health and Care Excellence (NICE), Agency for Healthcare Research and Quality (AHRQ) were searched. The search to find available guidelines was performed for the latest guidelines in English or Persian and in databases, such as MEDLINE, Web of Science, Embase, Scopus, ProQuest, Google scholar, and Magiran (SID) using keywords [Mesh].

Panel of experts

In the next step of the study, a specialized panel of experts in the physiologic birth program was formed using Delphi method in following stages.

First stage: Selection of panel members

We chose the experts using the purposive sample approach from among those who had a history of providing clinical services relevant to delivery and had involvement with physiologic birth programs (national instructors of physiologic birth, executive directors, midwives with clinical experience of physiologic birth, and gynecologists). The objectives of the study were explained to these experts by the research team, and they were invited to participate in the study.

Second stage: Asking questions from the panel members

In this stage, the panel members were asked to answer/explain the following open questions/comments in written or oral form.

- Express your experiences of the physiologic birth plan
- What are the obstacles to the implementation of the physiologic birth program?
- What strategies do you suggest for the better implementation of the physiologic birth program?

Third stage: Summarizing

Following the collection of the second stage participants' answers, duplicate responses were eliminated, and responses containing related concepts were combined. Then, the final results of

the opinions and suggestions of expert panel regarding the implementation of physiologic birth program were obtained.

Intervention design

The third stage of the research included the construction of the intervention design, which was based on the results of the qualitative phase of the interviews, a review of the instructions for carrying out the physiologic birth program, and the opinions of experts in the area of physiologic birth. Moreover, the research team prepared a summary based on a list of strategies obtained from the results of this stage for the improvement of physiologic birth program. This summary was sent to the experts for prioritizing the strategies (4th stage of Delphi). Finally, the research team decided on how to implement the intervention based on the most frequent priorities.

Quantitative phase of the study

A randomized controlled trial was used in this phase of the research to examine the impact of the physiologic birth program's intended intervention on maternal and newborn outcomes as well as mothers' experiences during labor.

Sample size and sampling method

Regarding the aim of the study, and the possible increase in the total score of childbirth experience in the intervention group compared to the control group by 15% in a previous study [19], and assuming the test power of 80%, $\beta=0.2$, $\alpha=0.05$, $s1=0.73$, $s2=0.271$ and $d=0.271$, we calculated the sample size via following formula to be 114 participants in each group. The sample size increased to 126 individuals in each intervention and control group after accounting for the likely 10% decline in the samples. This phase was a randomized controlled clinical trial with two intervention and control groups to investigate the effect of physiologic birth program on maternal and neonatal outcomes in healthcare centers of Ahvaz city in Iran. The researchers began the investigation based on the planned intervention after receiving the ethics committee's authorization and approval and registered the study in the Iranian Registry for Clinical Trials. To select the participants, a list of pregnant women was first prepared based on their electronic health records.

To allocate the participants to intervention group (modified approach to physiologic birth program), and the control group (routine approach to the physiologic birth program), permuted block randomization technique with a random block size of 4-6 (using the table of random

permutations) and an allocation ratio of 1:1 were used. The randomization list was prepared by a statistician. Group allocation was done using a randomized list created by an outside researcher who was unaware of the study aims, and the matching codes were maintained in sealed envelopes for the purpose of allocation concealment. Prior to commencement of the intervention, both the researchers and the participants were masked to group allocation. Considering the nature of the study, blinding was not possible, but the outcome assessors were blinded to the purpose of study. The intervention started after obtaining informed consent from the participants. The final and complete content, as well as the details of the intervention was designed in the study process, and after reviewing the results of the qualitative phase of the study, reviewing the literature, and obtaining the results of the panel of experts. The general procedure of intervention was based on the principles of physiologic birth. It included childbirth preparation courses during pregnancy for low-risk pregnant mothers, which started from the 20th week of pregnancy (based on the current national protocol in Iran) and continued until the process of labor and physiologic birth. In fact, midwives who had completed a 60-hour physiologic birth program recognized by the Ministry of Health from pregnancy through labor and delivery accompanied expectant mothers. The participants gave birth to their babies at Sina or Allameh Karami public hospitals where the physiologic birth program is currently being implemented.

The control group attended 8 sessions of childbirth preparation classes, and received no intervention. Finally, the maternal and neonatal outcomes, including the severity of labor pain, the duration of labor stages, the amount of oxytocin used, the perineum condition, postpartum bleeding, type of delivery, 1- and 5-minute Apgar scores, the duration of mother's hospitalization, breastfeeding in the first postpartum hour, hospitalization of the newborn, and the experiences of mothers with childbirth were compared in the two groups.

Inclusion criteria

Inclusion criteria were: willingness to participate in the study, having low-risk pregnancy (from 20th week of pregnancy), having singleton pregnancy, being aged 18-35-year-old, giving birth to a live and healthy fetus with cephalic presentation, and having a normal body mass index.

Exclusion criteria

Exclusion criteria were: any medical or obstetric problem that put women in a high-risk group in terms of pregnancy, and high-risk process of labor, and childbirth that prohibited physiologic birth.

Scales and data collection

The data collection tools included a demographic, and obstetric information questionnaire, labor and delivery status checklist based on mother's maternity records, and childbirth experience questionnaire. Before the intervention, the researcher filled out the demographic and obstetric questionnaire, which included questions about age, education, occupation, pre-pregnancy counseling status, intended and unintended pregnancies, last menstrual period (LMP), gestational age, birth date, and body mass index (BMI). The labor and delivery checklist included maternal and neonatal outcomes (severity of labor pain, duration of labor stages, amount of oxytocin used, perineal condition, postpartum bleeding, type of delivery, 1- and 5-minute Apgar scores, the duration of mother's hospitalization, breastfeeding in the first postpartum hour, and hospitalization of the newborn) was completed by a research assistant who was not aware of the objective of the study after delivery.

The childbirth experience questionnaire was developed by Dencker et al. in 2010. This tool measures the birth experience of primiparous women. It includes following areas: personal capacity, professional support, perceived security, and participation. The answers ranged from completely agree (score 1) to completely disagree (score 4). The questions that were answered based on a visual scale were converted into values ranging from 1 to 4. A better birthing experience is indicated by a higher score on this instrument. This tool's validity and dependability have been verified in populations speaking English, Spanish, Danish, and Malay. Furthermore, in the Iranian population, they were proven in the study by Ghanbari et al [19,20]. This tool was completed by the mother after giving birth (immediately or up to a maximum of one month).

Data analysis

Quantitative variables were reported as mean ± standard deviation, whereas qualitative variables were reported as number (percentage). The normality of quantitative variables was checked using the Shapiro-Wilk test. Chi-square test was used to check the relationship among qualitative variables, and independent t-test or its non-parametric equivalent was used to compare quantitative variables between two independent groups. According to the kind of outcome and the potential existence of confounding factors, regression models were employed to assess the efficiency of the intervention. The significance level for the above tests was considered to be smaller than 0.05. Data were analyzed using Stata software version 12.

Presentation of the program

The program was presented based on the principles of the public health program. The main stages of this program include the analysis of current context, goal setting, identification of the selected strategies, the identification of obstacles to the implementation of the program, interdepartmental cooperation, program design, program implementation, and program evaluation. In the present research, the qualitative, and Delphi phases were conducted through analyzing, targeting, and formulating selected strategies. The quantitative phase served as the foundation for the program's design and execution. SWOT analysis, departmental cross-pollination, and program review were all mentioned by the researchers.

The integration of the program into the Iranian health system

To integrate the proposed program into the health system of Iran, the format of Ministry of Health, was used. It is entitled as “The form for the integration of health programs into the country's health system”. The program overview, objectives, and strategies are all included in this form, along with the implementation model, a resource list, a list of support and service procedures, a description of the duties for each level of the program that will be integrated into the healthcare system, a list of program monitoring procedures, and a list of program evaluation indicators.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Validity and reliability of the mixed research

To ensure the validity of the mixed research, following measures were taken: choosing the right persons for data collection in the quantitative and qualitative phases, choosing the right sample size for quantitative and qualitative phases, selecting suitable participants for the qualitative phase, using the significant results of the quantitative phase in the qualitative phase by the purpose of providing further explanation and gaining a deeper understanding, integration and interpretation of the results of quantitative and qualitative phases with the aim of answering the mixed research question, and consensus of the research team members on the general objectives of the research, methods, and results.

DISCUSSION

This mixed method study was conducted for the first time in Iran to provide a physiologic birth intervention program which can be integrated into the health system. Based on the recommendations of WHO, the physiologic birth program is one of the main strategies for reducing the rate of cesarean section, and improving maternal and neonatal health [21,22]. Based on the guidelines of WHO for positive childbirth experiences, efficient programs are needed for the provision of services from pregnancy, labor, and delivery to postpartum period.[23] The physiologic birth program is only implemented in Iran via childbirth education programs offered at specified health facilities. This runs counter to WHO's recommendation that physiologic birth without intervention is not indeed implemented. The modified program developed in this study can help health planners and policy makers implement high-quality physiologic birth programs based on global recommendations.

This study has several strengths. Using a combination of quantitative and qualitative approaches, as opposed to when each is separately used, provides a better understanding of research questions.[24] The embedded design is a type of mixed approach in which one type of data set plays a supporting and necessary role for another type. Researchers use this approach when they have large research projects ahead. [25,26] As a consequence, the embedded mixed technique used in the qualitative phase prior to intervention design may provide thorough and efficient findings. A comprehensive review of present status of physiologic birth program was done via qualitative interviews with health service providers at managerial, executive and clinical levels to identify barriers and devise effective strategies. Moreover, a qualitative interview with mothers who have experienced physiologic childbirth which have had an accompanying midwife can reflect their positive and negative experiences of this program. Given that the Iranian healthcare system lacks an accompanying midwife and ongoing midwifery care, the findings of this research may be efficiently applied to the provision of conventional obstetric services in public facilities. The clinical trial conducted in this study involved a large sample size to prove the effectiveness of the intervention. Thus, when the program is proposed to managers and policy makers, it will be more likely to be implemented, and integrated into the health system.

The limitation of the study is that while the developed program in this study can be integrated into Iran's health system, it may not be generalized to other countries. Still, it can be implemented in

countries with similar health services or can be used in other countries after applying the necessary modifications.

Ethics Approval

This study was approved by Ethics Committee of Ahvaz Jundishapur University of Medical Sciences (Ref. ID: IR.AJUMS.REC.1401.050). The participants provided verbal and written informed permission, and it was made clear to them that they might leave the research at any moment while the data was being collected without facing any repercussions. They were ensured that all information would be kept confidential, and the results would be reported in aggregated form. The findings of the study were supposed to be provided to the beneficiaries in appropriate ways. These include academic articles, as well as national and international conferences. The findings could be presented to policymakers, related scientific associations, stakeholders or participants through formal or informal meetings at any time or place requested. Trial registration number IRCT20220406054438N1.

Authors' contributions

AM, PA, MI, SK, NA, EM, NS conceptualized the study. AM, PA, MI, SK, NA, EM, NS contributed to the design of study. AM drafted the manuscript. PA revised the manuscript. The authors read and approved the final manuscript.

Funding

The study was funded by Ahvaz Jundishapur University of Medical Sciences (grant number RHPRC-0103).

Competing interests

None declared.

Fig. 1. Sequential an embedded mixed method design

Fig.2 Study diagram

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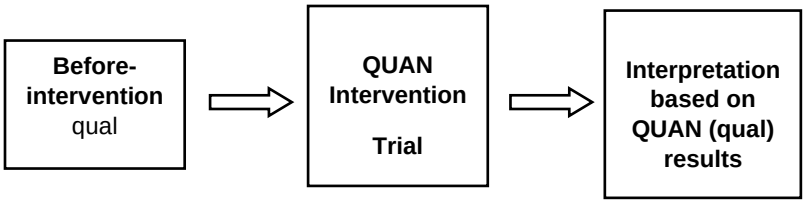

Fig. 1. Sequential an embedded mixed method design

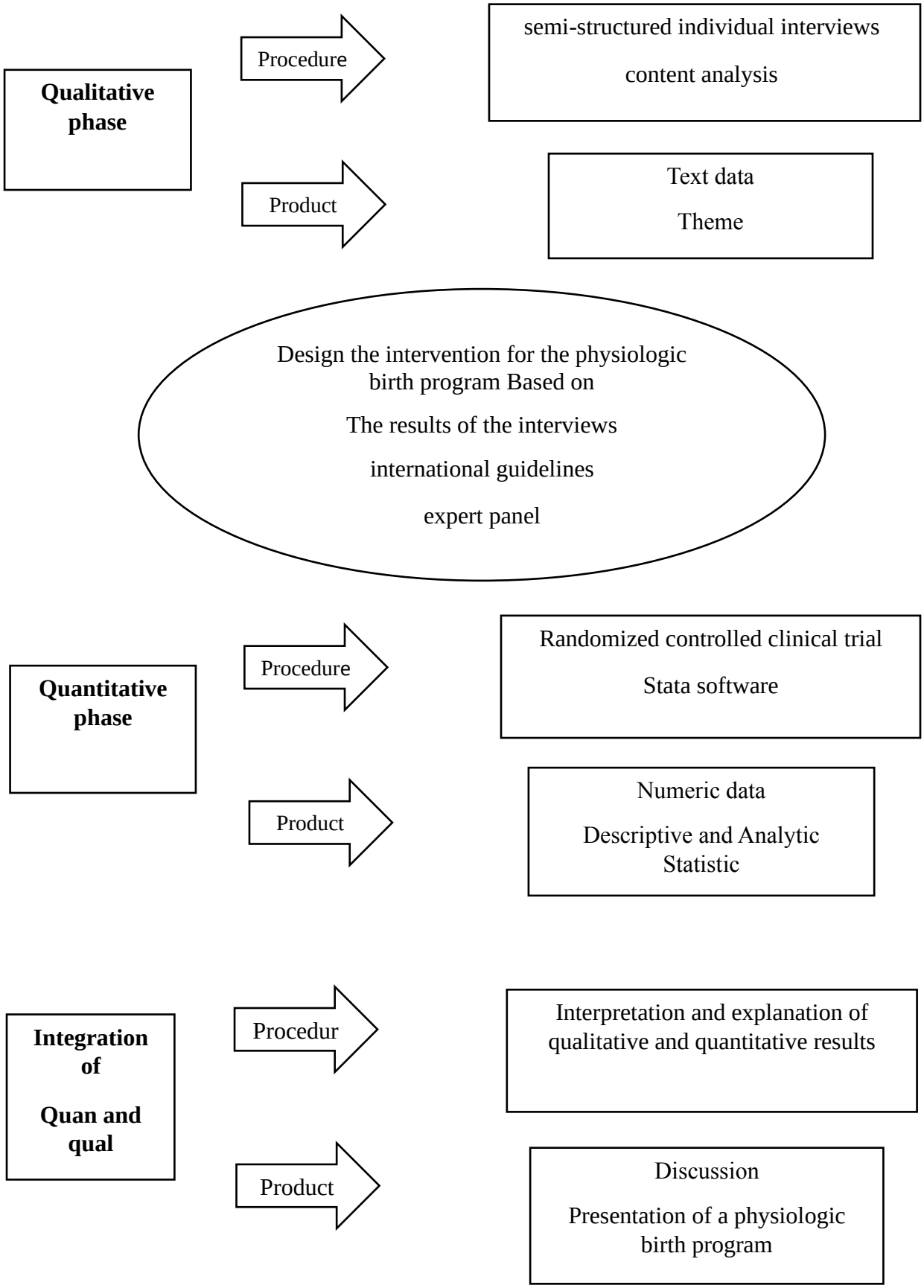

Fig.2 Study diagram