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Development of a modified physiological birth programme 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 WHO, promotion of physiological birth is a main strategy to reduce the rate of caesarean section and achieve Sustainable Development Goals. A modified version of the physiological birth programme 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 semistructured in-depth targeted interviews with the recipients and the providers of physiological birth programme services. Data analysis was performed using a conventional content analysis approach. Then, for designing the intervention, national and international guidelines of physiological birth were reviewed, and a panel of experts was convened using the Delphi method. A randomised controlled trial was used in the second phase of the research to examine the impact of the physiological birth programme's intended intervention on maternal and neonatal outcomes as well as mothers' experiences during labour. 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 physiological birth programme 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). 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.

Trial registration number 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 a physiological birth programme.
⇒ A clinical trial with a large sample size to show the effectiveness of the intervention.
⇒ The limitation of the study is that the modified programme could be generalised 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 the WHO statement, since 1985, the international healthcare community considered the ideal caesarean 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% 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 four to five 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 are 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 physiological birth programme in Iran revealed that evaluating the programme in terms of process is acceptable. However, analysis of the input, output and operational factors reveals that there is still room for improvement. The programme has to be improved in order to address its flaws, and a wide

range of stakeholders should work together to make this happen.[7–9] Studies in Iran have highlighted the need for effective clinical guidelines to strengthen the policies of health system by promoting the culture of physiological childbirth in order to improve its quality.[10–12]

However, unchanged vaginal delivery rate, which is 57% based on Iran's health development programme, indicates that the physiological birth programme could not effectively reduce the number of caesarean sessions and increase the number of vaginal deliveries based on predetermined objectives, even in public hospitals.[13–15] Therefore, it is imperative that the success of any programme in the healthcare system should be carefully studied, and the physiological birth programme is no exception.[16] A mixed-methods research to provide an intervention for the physiological birth programme has not yet been carried out in Iran. We thus sought to conduct a qualitative research to investigate the present state of the physiological birth programme in Iran. Using a mixed-methods study, we intended to design and implement an effective physiological birth programme 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 a physiological birth programme 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 physiological birth programme.
3. Determining the effect of the intervention based on a new physiological birth programme on maternal and neonatal outcomes.
4. Determining the effect of the intervention based on a new physiological birth programme on the experiences of mothers.
5. Developing a physiological birth programme 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 (figure 1).

This is an embedded study, including a qualitative phase aimed at explaining the experiences of recipients and providers of physiological birth programme services in Iran. Thus, to design the intervention for the physiological birth programme, the international guidelines for

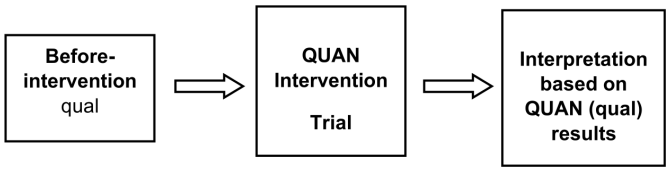

Figure 1 Sequential and embedded mixed-methods design.

physiological birth were reviewed, and a panel of experts was convened using the Delphi method. In order to assess the impact of the intervention based on the physiological birth programme 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 physiological birth programme which can be integrated into the Iranian health system (figure 2).

Qualitative phase of the study

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

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 generalisability were used to choose the samples. The research population consisted of service recipients (ie, women who had given birth around 6 weeks prior to the commencement of study and had participated in childbirth preparation classes and experienced physiological birth with an accompanying midwife) and service providers (ie, instructors of childbirth preparation classes, midwives, gynaecologists, doulas and executive directors).

Data collection

To collect qualitative data, in-depth and semistructured individual interviews were conducted after obtaining informed consent from the participants. The interviews were conducted by the first author of this 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

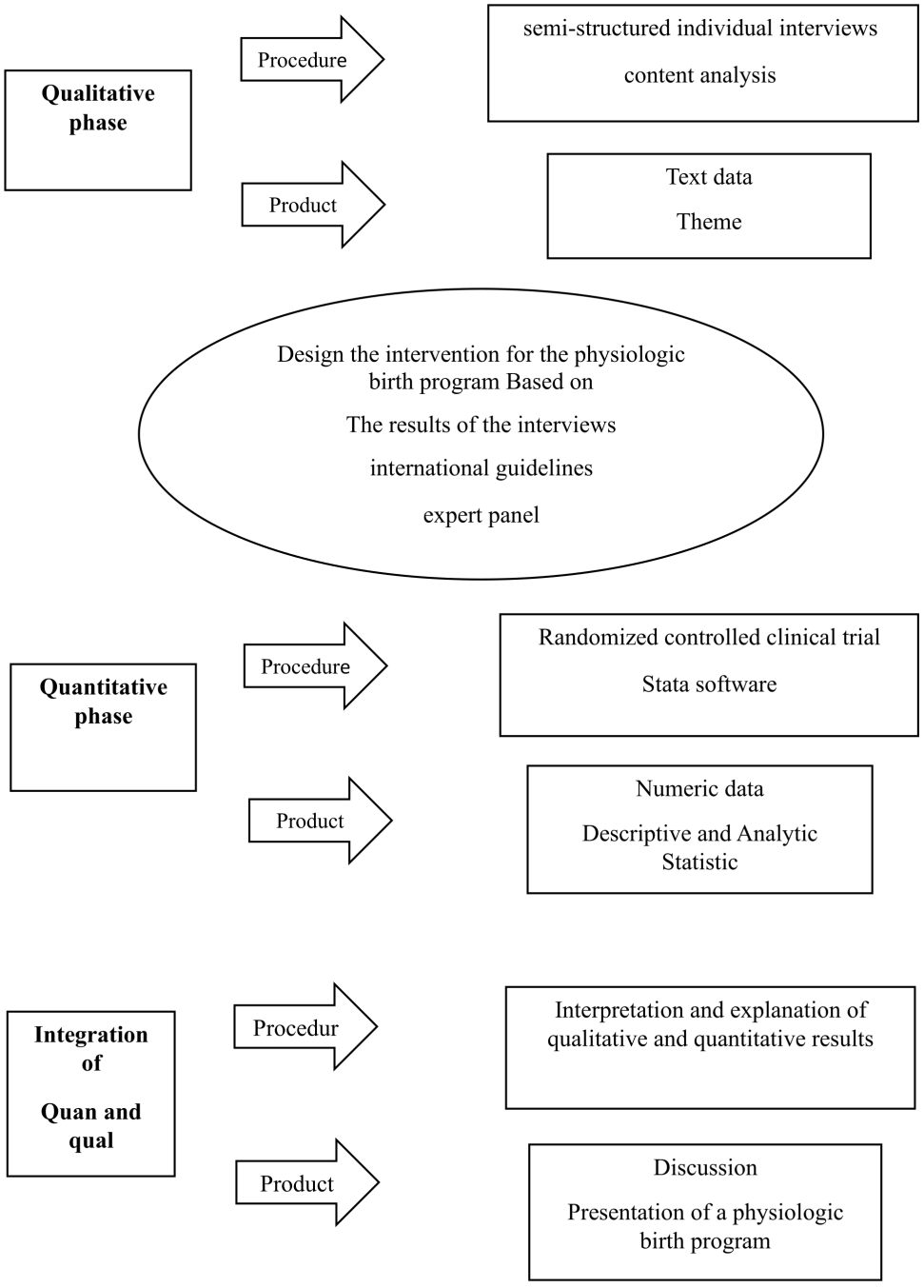

Figure 2 Study diagram.

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 physiological birth programme'. 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 was achieved.

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 (V.10). The four criteria of Lincoln *et al*[18] were used to increase the trustworthiness of the data. The credibility of the 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 physiological birth programme were searched and reviewed. In order to have access to these guidelines, clinical guideline databases, such as WHO Guidelines, the National Institute for Health and Care Excellence, and Agency for Healthcare Research and Quality, 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 (Medical Subject Headings).

Panel of experts

In the next step of the study, a specialised panel of experts in the physiological birth programme was formed using the Delphi method in the 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 physiological birth programmes (national instructors of physiological birth, executive directors, midwives with clinical experience of physiological birth and gynaecologists). 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 physiological birth plan.
- What are the obstacles to the implementation of the physiological birth programme?
- What strategies do you suggest for the better implementation of the physiological birth programme?

Third stage: summarising

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 the expert panel regarding the implementation of the physiological birth programme 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 physiological birth programme and the opinions of experts in the area of physiological 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 the physiological birth programme. This summary was sent to the experts for prioritising the strategies (fourth stage of the Delphi method). Finally, the research team decided on how to implement the intervention based on the most frequent priorities.

Quantitative phase of the study

A randomised controlled trial was used in this phase of the research to examine the impact of the physiological birth programme's intended intervention on maternal and newborn outcomes as well as mothers' experiences during labour.

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 with 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 via following the 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 randomised controlled clinical trial with two intervention and control groups to investigate the

effect of the physiological birth programme on maternal and neonatal outcomes in healthcare centres of Ahvaz city in Iran. The researchers began the investigation based on the planned intervention after receiving the ethics committee's authorisation 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 the physiological birth programme) and the control group (routine approach to the physiological birth programme), permuted block randomisation technique with a random block size of 4–6 (using the table of random permutations) and an allocation ratio of 1:1 was used. The randomisation list was prepared by a statistician. Group allocation was done using a randomised 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 blinded to group allocation. Considering 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, were designed in the study process, 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 physiological 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 labour and physiological birth. In fact, midwives who had completed a 60-hour physiological birth programme recognised by the Ministry of Health from pregnancy through labour and delivery accompanied expectant mothers. The participants gave birth to their babies at Sina or Allameh Karami public hospitals where the physiological birth programme is currently being implemented.

The control group attended eight sessions of childbirth preparation classes and received no intervention. Finally, the maternal and neonatal outcomes, including the severity of labour pain, the duration of labour stages, the amount of oxytocin used, the perineum condition, postpartum bleeding, type of delivery, 1 and 5 min Apgar scores, the duration of mother's hospitalisation, breast feeding in the first postpartum hour, hospitalisation 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 years old, giving birth to a live and healthy fetus with cephalic presentation, and having a normal body mass index (BMI).

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 labour, and childbirth that prohibited physiological birth.

Scales and data collection

The data collection tools included a demographic and obstetric information questionnaire, labour and delivery status checklist based on the 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 counselling status, intended and unintended pregnancies, last menstrual period, gestational age, birth date and BMI. The labour and delivery checklist that included maternal and neonatal outcomes (severity of labour pain, duration of labour stages, amount of oxytocin used, perineal condition, postpartum bleeding, type of delivery, 1 and 5 min Apgar scores, the duration of mother's hospitalisation, breast feeding in the first postpartum hour and hospitalisation 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 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-Homayi *et al*.[19 20] This tool was completed by the mother after giving birth (immediately or up to a maximum of 1 month).

Data analysis

Quantitative variables were reported as mean±SD, whereas qualitative variables were reported as number (percentage). The normality of quantitative variables was checked using the Shapiro-Wilk test. X^2 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 analysed using Stata software V.12.

Presentation of the programme

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

The integration of the programme into the Iranian health system

To integrate the proposed programme 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'. The programme 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 programme that will be integrated into the healthcare system, a list of programme monitoring procedures and a list of programme 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-methods research

To ensure the validity of the mixed-methods 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 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-methods research question, and a consensus of the research team members on the general objectives of the research, methods and results.

DISCUSSION

This mixed-methods study was conducted for the first time in Iran to provide a physiological birth intervention programme which can be integrated into the health system. Based on the recommendations of the WHO, the physiological birth programme is one of the main strategies for reducing the rate of caesarean section, and improving maternal and neonatal health.[21 22] Based on the guidelines of the WHO for positive childbirth experiences, efficient programmes are needed for the provision of services from pregnancy, labour and delivery to the postpartum period.[23] The physiological birth programme is only implemented in Iran via childbirth education programmes offered at specified health facilities. This runs counter to the WHO's recommendation that physiological birth without intervention is not indeed implemented. The modified programme developed in this study can help health planners and policymakers implement high-quality physiological birth programmes 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-methods approach in which one type of dataset 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-methods technique used in the qualitative phase prior to intervention design may provide thorough and efficient findings. A comprehensive review of the present status of the physiological birth programme 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 physiological childbirth who have had an accompanying midwife can reflect their positive and negative experiences of this programme. 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 programme is proposed to managers and policymakers, it will be more likely to be implemented and integrated into the health system.

The limitation of the study is that while the developed programme in this study can be integrated into Iran's health system, it may not be generalised 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.

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