Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Design, Implementation, and Evaluation of a Comprehensive Fear-of-Childbirth Management Program with an Interprofessional Approach

Protocol summary

Study aim
To determine the effectiveness of a comprehensive intervention package in reducing fear of childbirth and improving childbirth self-efficacy, maternal satisfaction, and childbirth outcomes.

Design
A randomized, controlled, parallel-group, double-blind clinical trial with assessor and data analyst blinding will be conducted among 60 pregnant women. Randomization will be performed using a computer-generated block randomization sequence.

Settings and conduct
The study will be conducted at prenatal care clinics, comprehensive health centers, and affiliated hospitals of Isfahan University of Medical Sciences, Iran. Eligible pregnant women will be recruited during routine antenatal care visits, randomly allocated to the intervention or control group, and followed from 28–30 weeks of gestation until childbirth.

Participants/Inclusion and exclusion criteria
Inclusion criteria Low-risk pregnant women, 28–30 weeks of gestation, W-DEQ ≥60, and willing to participate. Non-inclusion criteria High-risk pregnancy, indication for cesarean birth, severe psychiatric disorders, or withdrawal from the study.

Intervention groups
Participants will receive antenatal care based on a comprehensive intervention package including education, counseling, relaxation techniques, and use of a mobile application from 28–30 weeks of gestation until childbirth.

Main outcome variables
Fear of childbirth (W-DEQ), childbirth self-efficacy (CBSEI), and maternal satisfaction with vaginal birth.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220123053802N3**
Registration date: **2026-07-08, 1405/04/17**
Registration timing: **prospective**

Last update: **2026-07-08, 1405/04/17**
Update count: **0**

Registration date
2026-07-08, 1405/04/17

Registrant information
Name
soheila mohamadirizi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-23, 1405/07/01

Expected recruitment end date
2027-09-23, 1406/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Design, Implementation, and Evaluation of a Comprehensive Fear-of-Childbirth Management Program with an Interprofessional Approach

Public title
Design, Implementation, and Evaluation of a Comprehensive Fear-of-Childbirth Management Program
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
A fear of childbirth (FOC) score of 60 or higher (W-DEQ ≥60).
Exclusion criteria:
High-risk pregnancy Definite medical indication for cesarean section. .History of diagnosed severe psychiatric disorders. Severe physical illness preventing participation in the educational intervention Unwillingness to participate in the study
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible participants will be randomly allocated to either the intervention or the control group in a 1:1 ratio using computer-generated block randomization with variable block sizes of 4 and 6. The random allocation sequence will be generated by an independent researcher who is not involved in participant recruitment or outcome assessment. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes (SNOSE), which will be opened only after participant enrollment.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the educational and counseling nature of the intervention, blinding of participants, care providers, and investigators is not feasible. However, the outcome assessor and data analyst will remain blinded to group allocation throughout the study. Participants will be identified using unique codes, and group allocation information will not be disclosed to the outcome assessor or the data analyst until completion of the primary data analysis. This procedure is intended to minimize assessment and analysis bias.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Institute for Medical Research Development Islamic Republic of Iran
Street address
13th Floor, Block A, Ministry of Health and Medical Education Headquarters, Simaye Iran Street, between South Falamak and Zarafshan Streets, Shahrak-e Gharb (Qods Town), Tehran, Iran.
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tehran
Province
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Postal code
۱۴۱۹۶۹۳۱۱۱
Approval date
2026-05-19, 1405/02/29
Ethics committee reference number
IR.NIMAD.REC.1405.075

Health conditions studied

1

Description of health condition studied
fear of childbirth
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Fear of childbirth, childbirth self-efficacy, and maternal satisfaction.
Timepoint
Before the intervention, two weeks after the intervention, and immediately after childbirth.
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Mode of delivery
Timepoint
postpartum
Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group: Receipt of prenatal care based on a comprehensive intervention package including individual and group education, midwifery counseling, peer education, breathing and relaxation exercises, guided hospital visits, couple sessions, religious and spiritual content, and use of a mobile application, from 28–30 weeks of gestation until childbirth.

Category
Behavior

2

Description
Control group: Participants will receive routine antenatal care according to the national prenatal care guidelines of the Ministry of Health and Medical Education, without receiving the comprehensive Fear of Childbirth management program or the educational mobile application

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital

Full name of responsible person
Soheila mohamadirizi

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Isfahan University of Medical Scienc, Hezarjarib Ave, Isfahan Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
National Institute for Medical Research Development Islamic Republic of Iran

Full name of responsible person
Shahin Akhondzadeh

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No. 21, Beginning of Be'sat Street, West Fatemi Street, Tehran, Iran, National Institute for Medical Research Development (NIMAD).

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
National Institute for Medical Research Development Islamic Republic of Iran

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
National Institute for Medical Research Development of the Islamic Republic of Iran (NIMAD)

Full name of responsible person
Soheila mohamadirizi

Position
Assisstan professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Assistant Professor

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Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Publishable in the field of Midwifery

When the data will become available and for how long
Will be shared after completion of the study.

To whom data/document is available
Will be shared with researchers working in academic and scientific institutions after completion of the study.

Under which criteria data/document could be used
Will be shared with researchers working in academic and scientific institutions after completion of the study.

From where data/document is obtainable
After completion of the study, email addresses will be shared with applicants upon request.

What processes are involved for a request to access data/document
After completion of the study, applicants may request access to the files by contacting the provided email address.

Comments