Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the Effect of a Technology-Based Late-Pregnancy Childbirth Preparation Program on Childbirth Readiness, Fear of Childbirth, Childbirth Experience, and Mode of Delivery in Pregnant Women

Protocol summary

Study aim

Determining the Effect of a Technology-Based Late-Pregnancy Childbirth Preparation Program on Childbirth Readiness, Fear of Childbirth, Childbirth Experience, and Mode of Delivery in Pregnant Women

Design

A parallel-group, randomized controlled trial involving 70 participants (35 per group). Randomization is performed using block randomization with block sizes of 4 and 6 in a 1:1 allocation ratio, using RAS software.

Settings and conduct

Given the role of childbirth preparation in reducing fear of childbirth and promoting natural delivery, this randomized controlled trial with a control group will be conducted on 70 participants (35 per group) at comprehensive health centers and hospitals in Isfahan. Pregnant women aged 20–49 years with a gestational age of ≥36 weeks and 6 days who desire natural childbirth will, after providing informed consent, be allocated via block randomization (RAS software) to the intervention group (a technology-based program comprising multimedia content, self-care tools, consultation, and a chatbot) or the control group (routine care). Data will be collected using standardized questionnaires before and after the intervention and analyzed

Participants/Inclusion and exclusion criteria

Inclusion criteria: Desire for natural childbirth; a gestational age ≥36 weeks and 6 days; singleton pregnancy; access to smartphone and Internet Exclusion criteria: Severe hearing or visual impairment that prevents the use of the program’s audio and visual content,High-risk pregnancy such as preeclampsia

Intervention groups

Intervention group: Receiving a technology-based childbirth preparation program (multimedia content, self-care tools, online consultation, and chatbot) installed on mothers’ smartphones with training on its use Control group: Receiving routine pregnancy care

Main outcome variables

Childbirth Readiness; Fear of childbirth; Childbirth experience; Mode of delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260808070572N1**
Registration date: **2026-08-14, 1405/05/23**
Registration timing: **prospective**

Last update: **2026-08-14, 1405/05/23**
Update count: **0**

Registration date

2026-08-14, 1405/05/23

Registrant information

Name

Maryam Khalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3424 2020

Email address

maryamkhalili68@yahoo.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-20, 1405/06/29

Expected recruitment end date

2027-03-20, 1405/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the Effect of a Technology-Based Late-Pregnancy Childbirth Preparation Program on Childbirth Readiness, Fear of Childbirth, Childbirth Experience, and Mode of Delivery in Pregnant Women

Public title
The Effect of a Technology-Based Childbirth Preparation Program on Childbirth Outcomes
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Desire for Natural Vaginal Delivery Pregnant women aged 20-49 Gestational age 36 weeks and 6 days and above Iranian and resident of Isfahan Consent to participate in the study Single pregnancy Access to a smartphone, Internet, Desire to use it No mental or chronic illnesses (heart disease, lung disease, etc.) based on information from the Sib system(Apple Integrated System) Mental health screening (with the DASS questionnaire) Use of the desired content and program for at least 5 days
Exclusion criteria:
Presence of contraindications to normal (vaginal) delivery, as assessed by the attending physician Severe hearing or visual impairment that prevents the use of the program’s audio and visual content High-risk pregnancy (such as preeclampsia, placenta previa, active bleeding, etc.)
Age
From **20 years** old to **49 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Random block randomization using RAS (Random Allocation Software) with blocks of sizes 4 and 6 and a 1:1 allocation ratio. The unit of randomization is the individual. The allocation sequence is generated by a person not involved in recruitment and placed in sequentially numbered opaque sealed envelopes (allocation concealment). Envelopes are opened in the order of participant enrollment
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Secretariat of the Biomedical Research Ethics Committee Isfahan University of Medical Sciences Administrative Building No. 4, 2nd Floor Hezarjerib Street, University Campus, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2026-08-04, 1405/05/13
Ethics committee reference number
IR.MUI.NUREMA.REC.1405.060

Health conditions studied

1

Description of health condition studied
Childbirth Readiness
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Fear of Childbirth
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Childbirth Experience
ICD-10 code
ICD-10 code description

4

Description of health condition studied
Mode of Delivery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Fear of childbirth
Timepoint
Before the intervention and immediately after the intervention
Method of measurement
(Wijma Delivery Expectancy/Experience Questionnaire - WDEQ) A and B

Secondary outcomes

1

Description
Childbirth Readiness
Timepoint
Before the intervention and immediately after the intervention
Method of measurement
Childbirth Readiness Scale

2

Description
Childbirth Experience
Timepoint
Immediately after delivery
Method of measurement
Childbirth Experience Questionnaire (CEQ)

3

Description
Mode of delivery
Timepoint
Immediately after delivery
Method of measurement
By referring to the medical record

Intervention groups

1

Description
Intervention group: Mothers in the intervention group receive a technology-based childbirth preparation program specifically designed for late pregnancy (from 36 weeks of gestation onward until the onset of labor). The program is delivered through an interactive online educational-supportive environment based on mothers' preferences (extracted from the qualitative phase). It includes multimedia content (short 3- to 5-minute videos with downloadable Persian subtitles, audio podcasts, and infographics), self-care tools (smart calendar and reminders), a counseling system (text chat and discussion forum), and an intelligent chatbot that uses artificial intelligence to personalize the content and educational pathway according to each mother's needs, preferences, and pregnancy status.The educational content covers physical exercises, breathing techniques, relaxation training, psychological support, and non-pharmacological methods for labor pain management. Eighty percent of the main content is made available within the first five days, with the remaining content provided gradually until the time of birth. The researcher also continuously offers online educational, supportive, and counseling support and reminds mothers to use the content via telephone calls and SMS. The aim of the intervention is to enhance childbirth preparedness and promote safe natural childbirth.
Category
Other

2

Description
Control group: Receive routine pregnancy care according to the national protocol (including periodic prenatal visits at comprehensive health centers or clinics, physical examinations, routine laboratory tests, necessary ultrasounds, general prenatal education, and referral if needed). This group does not receive any additional technology-based educational-supportive intervention or childbirth preparation program.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Hamzeh Health Center
Full name of responsible person
Freshte Brekat
Street address
Amir Hamzeh Health Center, Opposite of Maskan Bank and Bazarcheh, 4th Street, Amir Hamzeh Town, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3775 7509
Email
freshtebarekat@yahoo.com

2

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
minoomovahedi
Street address
Al-Zahra (S) Medical Educational Center, Sofeh

Boulevard, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
75731-81746

Phone
+98 31 3822 0000

Email
alzahra@mui.ac.ir

3

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital

Full name of responsible person
Dr. Safoura Rouholamin

Street address
Shahid Beheshti Women's and Maternity Hospital, Ostad Motahhari Street, Pol-e Felezi, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
81848-53541

Phone
+98 31 3236 7001

Email
beheshti@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
معاونت تحقیقات و فناوری

Street address
Building No. 4, Vice-Chancellery for Research and Technology, Isfahan University of Medical Sciences, Hesar-e-Jarib Street, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Phone
+98 31 3668 7898

Email
research@mui.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan University of Medical Sciences

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
Esfahan University of Medical Sciences

Full name of responsible person
Maryam Khalili

Position
PhD Candidate in Reproductive Health and Sexual Health

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
No. 119, 1st Floor, Shahid Ali Akbari Alley, Modares Boulevard, Borujen, Chaharmahal and Bakhtiari Province, Iran

City
Broujen

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8871853775

Phone
+98 38 3423 2020

Fax

Email
maryamkhalili68@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Maryam Khalili

Position
PhD Candidate in Reproductive Health and Sexual Health

Latest degree
Master

Other areas of specialty/work
Midwifery

Street address
No. 119, 1st Floor, Shahid Ali Akbari Alley, Modares Boulevard, Borujen, Chaharmahal and Bakhtiari Province, Iran

City
Broujen
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8871853775
Phone
+98 38 3423 2020
Fax
Email
maryamkhalili68@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Maryam Khalili
Position
PhD Candidate in Reproductive Health and Sexual Health
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
No. 119, 1st Floor, Shahid Ali Akbari Alley, Modares Boulevard, Borujen, Chaharmahal and Bakhtiari Province, Iran
City
Broujen
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8871853775
Phone
+98 38 3423 2020
Fax
Email
maryamkhalili68@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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