Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Design, development and evaluation of an educational web application based on woman-centered care for childbirth preparation in pregnant women

Protocol summary

Study aim

1. Compare mean childbirth preparedness between groups at 4 weeks (adjusted for baseline). 2. Compare mean fear of childbirth at 4 weeks and 24h postpartum (adjusted for confounders). 1. Compare mean childbirth experience at 24h postpartum (adjusted for confounders). 2. Compare mean childbirth self-efficacy at 24h postpartum (adjusted for baseline). 3. Compare mean postpartum depression literacy at 4 weeks (adjusted for baseline). 4. Compare frequency of delivery type between groups.

Design

This randomized clinical trial with parallel groups and no blinding will be conducted on 70 pregnant women. Participants will be allocated to intervention and control groups in a 1:1 ratio using block randomization (blocks of 4 and 6) generated in RAS software by an independent person. The allocation will be concealed in sequentially numbered opaque envelopes, which will be opened in order of participants' enrollment.

Settings and conduct

A randomized parallel trial on pregnant women (24–32 weeks) will be conducted in Tabriz health centers (2025). Participants are allocated by block randomization to intervention (personalized web app) or control (routine care). Data are collected before, after intervention, and postpartum. No blinding is applied.

Participants/Inclusion and exclusion criteria

Inclusion: 24–32 weeks, singleton, literate, smartphone, app use ability, non-medical education. Exclusion: Pregnancy complications/diseases, multiples, cesarean indications, prior cesarean or classes, high-risk pregnancy.

Intervention groups

Intervention group:personalized web application will be used four weeks, supplemented with researcher-led online support. To ensure thorough content engagement, each section of the app includes questions.Control group Participants will receive only routine standard care

Main outcome variables

childbirth preparation fear of childbirth

General information

Reason for update

We registered [the study] in the IRCT, but we were supposed to start sampling in January 2025. However, due to the delay in the web development process, the probable date for the third phase of the study and the RCT is now projected for February 2027.

Acronym

IRCT registration information

IRCT registration number: **IRCT20171007036615N16**
Registration date: **2025-11-18, 1404/08/27**
Registration timing: **prospective**

Last update: **2026-10-14, 1405/07/22**
Update count: **1**

Registration date

2025-11-18, 1404/08/27

Registrant information

Name

عصمت مهرابی

Name of organization / entity

دانشگاه علوم پزشکی تبریز

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 0649

Email address

mehrabie@tbzmed.ac.ir

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date
2027-01-11, 1405/10/21
Expected recruitment end date
2027-06-20, 1406/03/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Design, development and evaluation of an educational web application based on woman-centered care for childbirth preparation in pregnant women

Public title
Design and evaluation of an educational web application based on woman-centered care for childbirth preparation
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Gestational age of 24 to 32 weeks Singleton pregnancy Literacy (ability to read and write) Ability to use a mobile application Not having a medical field education Possession of a smartphone
Exclusion criteria:
Development of any pregnancy complications, such as preeclampsia. Bleeding and intrauterine fetal death. Multiple pregnancy Presence of chronic diseases or conditions that are induced or exacerbated by pregnancy, such as hypertension, cardiovascular diseases, diabetes, preeclampsia, etc. Indications for cesarean section, such as placenta previa, non-cephalic presentations, abnormal fetal heart rate patterns, etc. History of cesarean section or uterine surgery/scarring. Previous participation in physiological childbirth classes. Abnormal pregnancy conditions, such as polyhydramnios, oligohydramnios, or intrauterine growth restriction (IUGR).
Age
From **15 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
One-half of the health centers will be selected, considering diverse geographical locations and socioeconomic levels. In total, five centers will be selected from different areas of Karaj (taking into account diversity in terms of socioeconomic status). A list of pregnant mothers is available in the 'Sib' Health Information System at the health centers. The researcher will attend the selected centers, prepare a list of potentially eligible individuals, and then contact them by phone. After assessing the inclusion and exclusion criteria, those who qualify will be given a brief explanation of the study's purpose. If they are willing to participate, they will be invited to an in-person session at a health center near their residence. Participants will be allocated to either the intervention or control group with a 1:1 ratio using block randomization, stratified by the number of previous births. A person not involved in the sampling will perform the allocation using RAS software with block sizes of 4 and 6. The allocation details will be written on paper and placed in sequentially numbered, opaque, sealed envelopes to ensure allocation concealment. The envelopes will be opened in the order of the participants' entry into the study. The mother's name will be written on the selected envelope, and she will be informed of her assigned group.
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
Research Ethics Committees of Tabriz University of Medical Science
Street address
South Shariati Street, Faculty of Nursing and Midwifery, Tabriz
City
tabriz
Province
East Azarbaijan
Postal code
5138947977
Approval date
2025-09-08, 1404/06/17
Ethics committee reference number
IR.TBZMED.REC.1404.435

Health conditions studied

1

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

2

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

Primary outcomes

1

Description
childbirth preparation score
Timepoint
Before the intervention and 4 weeks after the intervention
Method of measurement
Childbirth Readiness Scale(CRS)

2

Description
fear of childbirth score
Timepoint
Before the intervention and 4 weeks after the intervention and 24 hours after delivery
Method of measurement
Wijma delivery expectancy/experience questionnaire

Secondary outcomes

1

Description
childbirth experience score
Timepoint
24hours after delivery
Method of measurement
Childbirth Experiences (CEQ-2.0) 2.0 Questionnaire version

2

Description
Child Birth Self Efficacy score
Timepoint
Before the intervention and 24 hours after delivery
Method of measurement
Child Birth Self Efficacy questionnaire

3

Description
Postpartum depression literacy score
Timepoint
Before the intervention and 4 weeks after the intervent
Method of measurement
Postpartum depression literacy Scale (PoDLiS)

4

Description
Frequency of mode of delivery
Timepoint
24 hours after delivery
Method of measurement
Frequency of mode of delivery check list

Intervention groups

1

Description
Intervention group: The designed web application will be installed on the smartphones of participants in the intervention group. Its content will be personalized so that, at the beginning, users must enter information such as gestational age and their symptoms. Based on these settings, each user will access the section of the app that contains information relevant to their pregnancy condition. The researcher will train participants in the intervention group on how to use the app so they can fully utilize its content over four weeks. The researcher will also provide online support and guidance during this period. Throughout the intervention, the researcher (student) will maintain contact with participants via phone calls and text messages to remind them to use the relevant content at each stage, and will share their contact information for any questions. To ensure thorough engagement with the app content, a limited set of relevant questions will be designed to be answered before and after each section.
Category
Prevention

2

Description
Control group: They will receive routine care according to the national guidelines.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Torkiyan health center
Full name of responsible person
Dr Esmat Mehrabi
Street address
First Street, Opposite Hazrat Abolfazl Mosque, First Square (Falaké Aval), Gohardasht
City
karaj
Province
Alborz
Postal code
3159332972
Phone
+98 26 3442 0051
Email
alizadehniloofar70@gmail.com

2

Recruitment center
Name of recruitment center
Hazrat Ali Asghar Health Center
Full name of responsible person
Dr Esmat Mehrabi
Street address
Shabnam 2 Alley, At the corner of Valiasr Square, Baghestan Gharbi
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Karaj
Province
Alborz
Postal code
3127633745
Phone
+98 26 3430 4800
Email
alizadehniloofar70@gmail.com

3

Recruitment center
Name of recruitment center
Shahdaye Hesarak-e Bala Health Center
Full name of responsible person
Dr Esmat Mehrabi
Street address
Hesarak-e Bala, After the Gas Pump
City
Karaj
Province
Alborz
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3126789542
Phone
+98 26 3456 5667
Email
alizadehniloofar@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr kHOSRO Adibkia
Street address
Azadi St., Shahid Jediri St., Tabriz
City
tabriz
Province
East Azarbaijan
Postal code
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Phone
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Email
Alizadehniloofar70@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Esmat Mehrabi
Position
Ph.D in reproductive health
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
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Person responsible for scientific inquiries

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Web page address

Person responsible for updating data

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Email
b.mehrabi@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No further information is available.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available