Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of education based on needs assessment of pregnant mothers on infant health indicators and unplanned hospitalization of mother and infant up to six weeks after delivery

Protocol summary

Study aim
Studying the effect of needs-based education of pregnant mothers in pregnancy, childbirth, and breastfeeding care on infant health indicators and unplanned hospitalization of mother and infant up to six weeks after delivery

Design
This study is a two-group randomized clinical trial in which participants are randomly assigned to an intervention and control group; the intervention group will receive pregnancy, childbirth preparation, breastfeeding, and newborn care education in four sessions in addition to usual care, and the control group will receive usual care only.

Settings and conduct
This study will be conducted in the hospital's health education clinic, and due to the educational nature of the intervention, blinding is not possible.

Participants/Inclusion and exclusion criteria
Pregnant mothers aged 18 to 45 years and with a gestational age of more than 24 and less than 34 weeks who are eligible for education and do not have diabetes, high blood pressure, or heart disease that affect neonatal outcomes.

Intervention groups
For this group, training sessions will be held in 4 sessions per month on topics such as pregnancy care education (nutrition, danger signs, physical activity), childbirth preparation education, and breastfeeding education. Follow-up between sessions and sending weekly educational messages (short text with key points) - A counseling hotline will be provided to answer mothers' questions.

Main outcome variables
Maternal and infant health indicators - exclusive breastfeeding at 6 weeks, unplanned maternal and infant hospitalization

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260712070138N1**
Registration date: **2026-09-17, 1405/06/26**
Registration timing: **prospective**

Last update: **2026-09-17, 1405/06/26**
Update count: **0**

Registration date
2026-09-17, 1405/06/26

Registrant information
Name
Vajihe Biniaz
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-10-12, 1405/07/20
Expected recruitment end date
2027-03-11, 1405/12/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of education based on needs assessment of pregnant mothers on infant health indicators and unplanned hospitalization of mother and infant up to six weeks after delivery

Public title
Investigating the effect of education based on needs assessment of pregnant mothers on infant health indicators and unplanned hospitalization of mother and infant up to six weeks after delivery

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Educability (mental health) Pregnancy age greater than 24 and less than 34 weeks Maternal age 18 to 45 years No uncontrolled chronic diseases such as diabetes, blood pressure, and heart disease that affect neonatal outcomes Having written approval from a gynecologist to participate in the class

Exclusion criteria:
Delivery before 36 weeks (to control for the confounding effect of prematurity). Unwillingness to continue cooperation at any stage of the study Infants born weighing 2500 g or less Infants with major congenital anomalies requiring prolonged hospitalization Occurrence of pregnancy complications such as preeclampsia, gestational diabetes, or placenta previa that require special care and independently affect outcomes. Attendance at less than 75% of the educational sessions (in the test group). Stillbirth or death of the infant before the end of the follow-up period.

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **186**

Randomization (investigator's opinion)
Randomized

Randomization description
A random number table will be designed using Random Allocation Software. Write the group assignment on cards and place in opaque, sealed, numbered envelopes - the envelopes will be prepared by someone other than the principal investigator (e.g., a midwifery education expert). After the mother enters the study, the next envelope will be opened and her group will be determined.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Baqiyatallah University of Medical Sciences

Street address
18 Mofateh St., Vahid 5, Health Education Clinic, Imam Hossein Hospital Imam Hossein hospital health clinic

City
Mashhad

Province
Razavi Khorasan

Postal code
9155966736

Approval date
2026-06-29, 1405/04/08

Ethics committee reference number
IR.BMSU.REC.1405.045

Health conditions studied

1

Description of health condition studied
Pregnancy

ICD-10 code

ICD-10 code description
Z34

Primary outcomes

1

Description
Needs-based training

Timepoint
Before the intervention begins

Method of measurement
Training Needs Assessment Checklist

2

Description
Baby's weight at birth

Timepoint
The baby's first weight immediately after birth

Method of measurement
The first recorded weight of the baby immediately after birth in grams

3

Description
Complications of the neonatal period
Timepoint
Any health disorder in the first 28 days of life that requires diagnostic or therapeutic intervention.
Method of measurement
Diagnoses recorded in the file include jaundice requiring hospitalization and phototherapy, hypoglycemia, sepsis, seizures, hospitalization in the neonatal intensive care unit, pneumonia, diarrhea.

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Description
Unplanned hospitalization of the mother
Timepoint
Unexpected admission to hospital due to postpartum complications and early discharge up to 6 weeks postpartum.
Method of measurement
Recording cases of infant readmissions with a doctor's diagnosis, through records and telephone calls

5

Description
Unplanned hospitalization of a newborn
Timepoint
Any readmission of the infant after initial discharge from the hospital due to medical problems up to six weeks of age
Method of measurement
Recording of newborn readmissions by physician diagnosis, via telephone call and file

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to regular group and individual care, participants in this group will receive four monthly sessions of pregnancy, childbirth preparation, breastfeeding, and newborn care education. They will also be provided with a booklet and contact number for potential questions, and weekly educational text messages (short text with key points) will be sent. A counseling hotline will be provided to answer mothers' questions.
Category
Prevention

2

Description
Control group: Participants in this group receive only routine health center care (periodic checkups, general education) - they do not receive any additional intervention from the researcher.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein hospital health clinic
Full name of responsible person
Vajihe Biniaz
Street address
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Sponsors / Funding sources

1

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Full name of responsible person
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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
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Vajihe Biniaz
Position
Profesor
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Person responsible for updating data

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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