Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

The effect of educational intervention based on the health belief model on breastfeeding self. efficacy of mothers referring to the health centers in Qazvin

Protocol summary

Study aim

General objective: Determining the effect of educational intervention based on the health belief model on breastfeeding self. efficacy in patients referring to Qazvin health centers

Design

A clinical trial with control group with randomized allocation on 120 pregnant mothers will be conducted. Also, a random allocation sequence generator software will be implemented to randomize the four. factor block design.

Settings and conduct

All health centers in Qazvin are considered as clusters. eligible people who are willing to participate in the study in an accessible way will be registered . Then at the second stage, the participants will be assigned randomly into two groups by four. factor randomized block design

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Being interested in participating in the study 2. Being in the age range of 18. 40 years 3. Having a gestational age of over 36 weeks 4. Having a singleton pregnancy 5. Having a low. risk pregnancy 6. Being at least literate 7. Having the ability to use internet software Exclusion criteria: 1. If the mother is not willing to participate in the study 2. Contraindications to breastfeeding after childbirth such as: major depression, HIV infection, untreated tuberculosis, breast diseases, and taking drugs contraindicated during breastfeeding and etc.

Intervention groups

In the present study, the intervention is implemented as four 90min. sessions of breastfeeding group training based on the components of the health belief model through Skyroom virtual network. the sessions are held once a week during pregnancy. The control group will receive routine prenatal care.

Main outcome variables

Perceived sensitivity component, perceived intensity component, perceived benefit component, perceived barriers component, practice guide component, breastfeeding self. efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210803052064N1**
Registration date: **2021-09-14, 1400/06/23**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-14, 1400/06/23**
Update count: **0**

Registration date

2021-09-14, 1400/06/23

Registrant information

Name

Fatemeh Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3257 7895

Email address

fmohammadiqums@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2023-08-23, 1402/06/01

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

Scientific title
The effect of educational intervention based on the health belief model on breastfeeding self. efficacy of mothers referring to the health centers in Qazvin

Public title
The effect of health belief model. based education on breastfeeding self. efficacy
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Being interested in participating in the study Being in the age range of 18. 40 years Having a gestational age of over 36 weeks Having a singleton pregnancy Having a low. risk pregnancy Being at least literate Having the ability to use internet software
Exclusion criteria:
If the mother is not willing to participate in the study Contraindications to breastfeeding after childbirth such as: major depression, HIV infection, untreated tuberculosis, breast diseases, and taking drugs contraindicated during breastfeeding and etc.
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Given that there are two training methods (one based on the health belief model and the other a routine breastfeeding training), four. factor randomized block design will be used for random allocation. The following 6 four. factor blocks are possible: (Aaaa, aaAA, AaAa, aAaA, AaaA, AAaa). Random allocation sequence generator software will be used to determine the allocation sequence by four. factor randomized block design. When sampling, the samples will be placed in control and intervention groups, according to the written order.
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 Qazvin University of Medical Sciences
Street address
Faculty of Nursing and Midwifery, University of Medical Sciences, Bahonar Blvd, Qazvin, IRAN.
City
Qazvin
Province
Qazvin
Postal code
3419759811
Approval date
2021-08-05, 1400/05/14
Ethics committee reference number
IR.QUMS.REC.1400.178

Health conditions studied

1

Description of health condition studied
Breastfeeding self. efficacy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Breastfeeding Self. Efficacy
Timepoint
Measuring the breastfeeding self. efficacy at the beginning of the study. before the intervention and at the first, fourth, and sixth weeks after delivery, after breastfeeding training based on the health belief model
Method of measurement
Brief form of breastfeeding self. efficacy questionnaire BSES. SF Dennis and exclusive breastfeeding assessment tool based on the components of the health belief model

Secondary outcomes

1

Description
Exclusive breastfeeding
Timepoint
Surveying the exclusive breastfeeding before the start of the study and at the first, fourth and, sixth weeks after delivery, after the start of breastfeeding training based on the health belief model

Method of measurement
Exclusive breastfeeding assessment tool based on the components of the health belief model

Intervention groups

1

Description
Intervention group: Breastfeeding group training based on the health belief model through Skyroom virtual network for pregnant mothers, four 90min. sessions once a week taught by a midwife.
Category
Behavior

2

Description
Control group: Receives routine breastfeeding training.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Qazvin Health Centers
Full name of responsible person
Fatemeh Mohammadi
Street address
No. 10, Kaj 16th Alley, 4th District, Imam Khomeini Av, Mohammadiyeh, Qazvin, IRAN
City
Mohammadiyeh
Province
Qazvin
Postal code
3491737895
Phone
+98 28 3257 7895
Email
fmohammadiqums@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Zinat Jourabchi
Street address
Faculty of Nursing and Midwifery, University of Medical Sciences, Bahonar Blvd, Qazvin, IRAN
City
Qazvin
Province
Qazvin
Postal code
3419759811
Phone
+98 28 3333 6003
Email
zjourabchi@qums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Zinat Jourabchi
Position
Consultant
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Faculty of Nursing and Midwifery, University of Medical Sciences, Bahonar Blvd, Qazvin, IRAN
City
Qazvin
Province
Qazvin
Postal code
3419759811
Phone
+98 28 3333 6003
Email
zjourabchi@qums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Zinat Jourabchi
Position
Consultant

Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Faculty of Nursing and Midwifery, University of Medical Sciences, Bahonar Blvd, Qazvin, IRAN
City
Qazvin
Province
Qazvin
Postal code
3419759811
Phone
+98 28 3333 6003
Email
zjourabchi@qums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Fatemeh Mohammadi
Position
Student
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
No. 10, Kaj 16th Alley, 4th District, Imam Khomeini Av, Mohammadiyeh, Qazvin, IRAN
City
Mohammadiyeh
Province
Qazvin
Postal code
3491737895
Phone
+98 28 3257 7895
Fax
Email
Fmohammadiqums@gmail.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