

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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.

AgeFrom **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

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No. 10, Kaj 16th Alley, 4th District, Imam Khomeini Av, Mohammadiyeh, Qazvin, IRAN

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Zinat Jourabchi

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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

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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Zinat Jourabchi

Position

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Latest degree

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Other areas of specialty/work

Midwifery

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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

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

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