

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The survey on impact of educational intervention on exclusive breastfeeding in primiparous women based on Theory of Planned Behavior

Protocol summary

Study aim

Determining the impact of educational intervention on exclusive breastfeeding in primiparous women based on Theory of Planned Behavior

Design

Clinical trial with control group; 150 ladies; Randomized.

Settings and conduct

Pre-test is performed by completing the exclusive breastfeeding questionnaire by intervention and control group. Breastfeeding education is provided in 4 sessions for the intervention group by lecture, question and answer method. The post-test is performed six months after delivery by completing the questionnaire. The location of this study is at Qom Health Center.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The first pregnancy lady, The last three months of pregnancy, Iranian, Literate, Resident of Qom; Exclusion criteria: There is a prohibition of breastfeeding.

Intervention groups

Intervention and control groups receive routine breastfeeding education at the health center. In addition to routine education, the intervention group is given breastfeeding education for 6 hours in 4 sessions.

Main outcome variables

Attitude scores, abstract norms, perceived behavioral control, behavioral intention and behavior.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181104041545N1**

Registration date: **2019-03-09, 1397/12/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-09, 1397/12/18**

Update count: **0**

Registration date

2019-03-09, 1397/12/18

Registrant information

Name

Seyedehzahra Haddad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3882 7732

Email address

zhadad@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-19, 1396/07/27

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The survey on impact of educational intervention on exclusive breastfeeding in primiparous women based on Theory of Planned Behavior

Public title

Exclusive breastfeeding

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant lady The first pregnancy The last three months of pregnancy Literate Iranian Resident of Qom

Exclusion criteria:

There is a prohibition of breastfeeding.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

There were 150 pregnant women who had criteria for entering the study; according to the list of apple systems, they were randomly assigned to intervention and control groups. The first 75 people are in the control group and the next 75 people are in the intervention group. We call the people to come to the health center and complete the breastfeeding exclusive breastfeeding questionnaire.

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 Qom University of Medical Sciences

Street address

Qom University of Medical Sciences, Saheli street

City

Qom

Province

Ghous

Postal code

3713649373

Approval date

2017-09-18, 1396/06/27

Ethics committee reference number

IR.MUQ.REC.1396.71

Health conditions studied**1****Description of health condition studied**

Exclusive breastfeeding

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Attitude score in exclusive breastfeeding questionnaire between intervention and control groups

Timepoint

Complete the questionnaire before the intervention and six months after delivery

Method of measurement

Exclusive breastfeeding questionnaire

2**Description**

Score of abstract norms in exclusive breastfeeding questionnaire between intervention and control groups

Timepoint

Complete the questionnaire before the intervention and six months after delivery

Method of measurement

Exclusive breastfeeding questionnaire

3**Description**

Perceived Behavioral Control Score in the exclusive breastfeeding questionnaire between intervention and control groups

Timepoint

Complete the questionnaire before the intervention and six months after delivery

Method of measurement

Exclusive breastfeeding questionnaire

4**Description**

Behavioral intention score in exclusive breastfeeding questionnaire between intervention and control groups

Timepoint

Complete the questionnaire before the intervention and six months after delivery

Method of measurement

Exclusive breastfeeding questionnaire

5**Description**

Behavioral score in exclusive breastfeeding questionnaire between intervention and control groups

Timepoint

Complete the questionnaire before the intervention and

six months after delivery
Method of measurement
Exclusive breastfeeding questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Holding four 90-minute sessions include breastfeeding benefits, how to brew and breed mother's milk, compounds and changes of mother's milk, lactating mother's diet, the correct method of lactating, Common problems in breastfeeding and provide the right solution.

Category

Behavior

2

Description

Control group: Get routine care by health center staff.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Qom Health Center

Full name of responsible person

Reza Karemloufar

Street address

20 m Shahid Beheshti, Imam Khomeini street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ghous University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Seyedehzahra Haddad

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

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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