Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 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

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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
Ghoum

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

Ghoum University of Medical Sciences

Full name of responsible person

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dr.hosseinsaghafi@gmail.com

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ghoum 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

Ghoum 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

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person
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Position
Full Professor

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Ph.D.

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Health Promotion

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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