Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of education based on the theory of self-efficacy on promotion of health literacy and exclusive breastfeeding among pregnant women referred to health centers.

Protocol summary

Study aim

Evaluate the effect of educational intervention based on theory of self-efficacy on Health Literacy and exclusive breastfeeding self-efficacy in pregnant women in health centers – Mashhad

Design

This study was experimental conducted on 90 pregnant women referred to comprehensive healthcare centers of Mashhad. Before the intervention, standard questionnaires on lactation self-efficacy and health literacy were completed by the mothers of the two groups. Then, Educational intervention was conducted for intervention group.Three months after the intervention, the questionnaires were completed again in two groups. Considering the fact that mothers were breastfeeding, the exclusive breastfeeding status was measured by two questionnaires.

Settings and conduct

This study was conducted on 90 pregnant women referred to comprehensive healthcare centers of Mashhad. The subjects were selected from No. 1, 2, 5, and Samen comprehensive healthcare centers of Mashhad, through multistage cluster random sampling method. Four health centers were randomly selected from each cluster (a total of 16 comprehensive healthcare centers).A total of 16 health centers were sampled, 8 were in the intervention group and 8 in the control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study; First pregnancy; Gestational age of 32 weeks and more; The ability to read and write; Iranian nationality. Non-entry criteria: breast abnormalities in mother; The absence of a training session.

Intervention groups

Educational intervention for intervention group based on self-efficacy theory and health literacy strategies on exclusive breastfeeding was conducted during three 90-minute training sessions for pregnant mothers.

Main outcome variables

Exclusive breastfeeding; Self-efficacy; Health literacy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160710028863N25**
Registration date: **2018-04-07, 1397/01/18**
Registration timing: **retrospective**

Last update: **2018-04-07, 1397/01/18**
Update count: **0**

Registration date

2018-04-07, 1397/01/18

Registrant information

Name

Nooshin Peyman

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences.

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date
2015-11-06, 1394/08/15
Actual recruitment start date
2015-07-23, 1394/05/01
Actual recruitment end date
2015-11-06, 1394/08/15
Trial completion date
empty

Scientific title
The effect of education based on the theory of self-efficacy on promotion of health literacy and exclusive breastfeeding among pregnant women referred to health centers.

Public title
Health literacy and exclusive breastfeeding self-efficacy in pregnant women.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study First pregnancy Gestational age of 32 weeks and more The ability to read and write Iranian nationality.
Exclusion criteria:
Breast abnormalities in mother.
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Actual sample size reached: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomized assignment of samples, five folded paper cards were used. The name of each health center was registered on each card. Sampling centers were randomly selected among five health centers in Mashhad including centers No. 1,2, Samen and five Mashhad. The two centers, Health Centers 2 and Samen, were randomly assigned to the intervention group and centers 1 and 5 were assigned as the control group.
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 Mashhad University of Medical Sciences
Street address
School of Health, Daneshgah18 Avenue, Danshgah Street, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9137673119
Approval date
2016-05-30, 1395/03/10
Ethics committee reference number
IR.MUMS.AC.REC1395.319

Health conditions studied

1

Description of health condition studied
Exclusive breastfeeding
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Health literacy
Timepoint
Before intervention and three months after the intervention
Method of measurement
Maternal health literacy questionnaire

2

Description
Self-efficacy
Timepoint
Before intervention and three months after the intervention
Method of measurement
Lactation self-efficacy questionnaire

Secondary outcomes

1

Description
Exclusive breastfeeding
Timepoint
Three months after intervention

Method of measurement
Labbok breastfeeding level questionnaire

Intervention groups

1

Description
Intervention group: The implementation of three training sessions on breastfeeding (a total of 180 minutes, During four sessions with titles based on the theory of self-efficacy and health literacy)
Category
Behavior

2

Description
In the control group the intervention has not been implemented.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers affiliated by Mashhad University of Medical Sciences
Full name of responsible person
Nooshin Peyman
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
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University of Medical Sciences Headquarters, Daneshgah avenue
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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
Vice chancellor for research, Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Elham Charoghchian Khorasani
Position
Master student of Health Education and Health Promotion
Latest degree
Master
Other areas of specialty/work
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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
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable