

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 Jul 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)

##### Phone

+98 915 502 6195

##### Email address

peymann@mums.ac.ir

##### 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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School of Health, Daneshgah18 Street, Danshgah Avenue, Mashhad

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peymann@mums.ac.ir

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http://hehpdept.mums.ac.ir

## 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

##### Street address

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

Health Promotion

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## Person responsible for scientific inquiries

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Nooshin Peyman

**Position**

PhD in Health Education and Health Promotion

**Latest degree**

Ph.D.

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## Person responsible for updating data

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Nooshin Peyman

**Position**

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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