

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### The effect of parents education on knowledge, altitude, practice and patterns of breastfeeding until four month.

#### Protocol summary

##### Summary

1)Objectives of the study The study aims to assess the effects of parents' education on their knowledge, attitude and practice pants and the pattern of breastfeeding until four months. 2)Design of the study This research is a non-blinded randomized clinical trial on two groups of parents intervention and control groups (n=66) who were randomized based on table of random figure. 3)Setting Parents in two groups of intervention and control who have inclusion criteria and were randomized based on table of random figure. The intervention group will be taught in two 40-minuth sessions a week about benefits of breastfeeding and harms of formula and correct position and how to help the mother in breastfeeding by father. The control group will be managed as routine. The knowledge, attitude and practice of participants in two groups will be measured by the questionnaires before and after 4 months. The data will be analyzed and compared before and after intervention as well as between two groups. 4) Participants The participants in the study are fathers and mothers who referred to Rastravesh health center, and have infants aged 3-5 days and have the following inclusion and exclusion criteria. sample size of 66 people will be placed randomly allocated in to two groups  
Inclusion Criteria for mothers: Being Iranian; Speaking in Persian; residency in Karaj city; literacy; Being nulliparous; No known medical conditions and mental illness; birth of a singleton and Healthy infant; have no obstacle for infant' breastfeeding. Inclusion Criteria for Fathers: Being Iranian; Speaking in Persian; residency in Karaj city; literacy. Exclusion criteria for participation: Unwillingness to continue cooperation with researcher; Hospitalization of the infant or mother for medical condition; Death of relatives in a period of study; Parents' separation from baby; Taking contraindicated medicines for breastfeeding by mothers; Death of infant; not Start feeding baby with breast milk during the first visit; Use of pacifiers; Unwanted pregnancy.

5)Intervention The intervention group will be taught in two 40-minuth sessions a week about benefits of breastfeeding and harms of formula and correct position and how to help the mother in breastfeeding by father. Then the knowledge, attitude and practice of participants in two groups will be measured by the questionnaires before and immediately after intervention and after 4 months. The data will be analyzed and compared before and after intervention in two groups. 6)Main outcome measures The knowledge, attitude and practice of participants in two groups will be measured by the questionnaires before and after 4 months. The data will be analyzed and compared before and after intervention as well as between two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201508248801N10**

Registration date: **2016-08-31, 1395/06/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-08-31, 1395/06/10

##### Registrant information

##### Name

Masoumeh Simbar

##### Name of organization / entity

Shahid Beheshti University for Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8820 2517

##### Email address

msimbar@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**  
**Funding source**  
Chancellor of research Shahid Beheshti University of  
Medical Sciences

**Expected recruitment start date**  
2015-11-22, 1394/09/01

**Expected recruitment end date**  
2016-01-21, 1394/11/01

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
The effect of parents education on knowledge, altitude,  
practice and patterns of breastfeeding until four month.

**Public title**  
The effect of parents education on knowledge, altitude,  
practice and patterns of breastfeeding.

**Purpose**  
Health service research

**Inclusion/Exclusion criteria**  
Inclusion Criteria for mothers: Being Iranian; Speaking in  
Persian; residency in Karaj city; literacy; Being  
nulliparous; No known medical conditions and mental  
illness; birth of a singleton and Healthy infant; have no  
obstacle for infant, breastfeeding. Inclusion Criteria for  
Fathers: Being Iranian; Speaking in Persian; residency in  
Karaj city; literacy. Exclusion criteria for participation:  
Unwillingness to continue cooperation with researcher;  
Hospitalization of the infant or mother for medical  
condition; Death of relatives in a period of study;  
Parents' separation from baby; Taking contraindicated  
medicines for breastfeeding by mothers; Death of infant;  
not start feeding baby with breast milk during the first  
visit; Use of pacifiers; Unwanted pregnancy.

**Age**  
From **10 years** old to **49 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **66**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**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

Ethical committee of Shahid Beheshti University of  
Medical Sciences

##### Street address

Medical Sciences University of Shahid Beheshti  
Nursing and Midwifery faculty of Shahid Beheshti, Vali  
Asr intersection prayer in front of the Rajai Hospital  
Beheshti Department of Nursing and Midwifery

##### City

Tehran

##### Postal code

1985717443

##### Approval date

2015-11-01, 1394/08/10

##### Ethics committee reference number

SBMU2.REC.1394.162

## Health conditions studied

### 1

#### Description of health condition studied

P92.5 Neonatal difficulty in feeding at breast

#### ICD-10 code

P92.5 Neon

#### ICD-10 code description

Neonatal difficulty in feeding at breast

## Primary outcomes

### 1

#### Description

Knowledge

#### Timepoint

Before intervention and Four month after the training  
intervention

#### Method of measurement

Assess parents' knowledge about Breastfeeding  
Questionnaire

### 2

#### Description

Attitude

#### Timepoint

Before intervention and Four month after the training  
intervention

#### Method of measurement

Assess parents' Attitude about Breastfeeding  
Questionnaire

### 3

#### **Description**

Practice

#### **Timepoint**

Before intervention and Four month after the training intervention

#### **Method of measurement**

Assess parents' Performance -behavior about Breastfeeding Questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Two 40-minute sessions Within a week of training That includes an explanation about the benefits of breastfeeding and how to properly breastfeed As well as face to face and direct training to mother and training to fathers on how to help encourage breastfeeding and help mother in planning or participating in other activities to provide time off for breast-feeding mother at night.

#### **Category**

Prevention

#### 2

#### **Description**

Breast-feeding mothers in the control group is training as usual. Fathers are not in this band.

#### **Category**

Prevention

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

Rastravesh Health center affiliated with Alborz University

##### **Full name of responsible person**

Farideh Panahi

##### **Street address**

Street martyr Beheshti, after Taleghani intersection, next to pool knowledge, Rastravesh health centers

##### **City**

Karaj

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

#### **Full name of responsible person**

Afshin Zarghil

#### **Street address**

Besides of Taleghani Hospital, Shahid Aarabi Street, Yaman Street, Shahid Chamran Highway

#### **City**

Tehran

#### **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, Shahid Beheshti University of Medical Sciences

#### **Proportion provided by this source**

100

#### **Public or private sector**

empty

#### **Domestic or foreign origin**

empty

#### **Category of foreign source of funding**

empty

#### **Country of origin**

#### **Type of organization providing the funding**

empty

### **Person responsible for general inquiries**

#### **Contact**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Farideh Panahi

##### **Position**

Master of Midwifery

##### **Other areas of specialty/work**

##### **Street address**

Unit 4 , Zarin building, No.9, 6th Street, 1St block, 3rd phase, Gohardasht

##### **City**

Karaj

##### **Postal code**

Iran

##### **Phone**

+98 26 3442 7513

##### **Fax**

##### **Email**

f.panahi53@gmail.com

##### **Web page address**

3148743386

### **Person responsible for scientific inquiries**

#### **Contact**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Masoumeh Simbar

##### **Position**

PhD

**Other areas of specialty/work****Street address**

Nursing and Midwifery faculty of Shahid Behshti,  
Research Department

**City**

Tehran

**Postal code****Phone**

+98 21 8865 5378

**Fax****Email**

msimbar@yahoo.com

**Web page address****City**

Karaj

**Postal code**

3148743386

**Phone**

+98 26 3442 7513

**Fax****Email**

f.panahi53@gmail.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Farideh Panahi

**Position**

Master of Midwifery

**Other areas of specialty/work****Street address**

Unit 4, Zarin building, No.9, 6th Street, 1St block, 3rd  
phase, Gohardasht

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*