

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

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Karaj

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Iran

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Fax

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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

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Tehran

Postal code**Phone**

+98 21 8865 5378

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msimbar@yahoo.com

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3148743386

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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