

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Effect of home visit on mothers perceived social support and continue exclusive breastfeeding

Protocol summary

Summary

This study aims to determine the effect of home visits on mothers' perceived social support and continuation of exclusive breastfeeding with mother breast milk. The present study is a randomized clinical trial carried out on two groups of nulliparous women: treatment and control. A questionnaire is used to measure perceived social support for mothers and continual exclusive breastfeeding with mother breast milk. Balanced Block Randomization sampling method is employed to randomly separate the women who entered the study into two groups. The number of samples in eight health centers is distributed equally. In order to randomly allocate the subjects, central telephone randomization is used. One hundred and eight prim parous breastfeeding mothers with 3 to 5- days breast-fed infants who have not received any food except mother milk and met the criteria for entering into the study will be selected. Inclusion criteria include such factors as mothers with an Iranian nationality, lack of physical and mental chronic debilitating diseases in mothers, which is the sole reason for the cessation of inclusive breastfeeding, mothers who are not working at health centers, mothers with 3 to 5-day-old infants who use breastfed their baby so far, and the child's lack of illness, which is a reason for the cessation of breastfeeding exclusively. Exclusion criteria include children and mothers who, due to illness during the study, are not able to breastfeed, and mothers who use lactation pump to feed their infants. In the treatment group, in order to visit homes at the end of first to sixth months, including six home visits, it is coordinated with mothers by phone, in advance, and emphasized that fathers and any relatives involving in the breastfeeding should also attend the training. To facilitate this, it is tried that training will be conducted when father is at home such as in the evenings or on holidays. The intervening people will be identified in the first visit by asking mothers' some questions. In home visit, the benefits of breastfeeding, the disadvantages of artificial

milk, making skin contact between mother and baby, how to help mothers in breastfeeding by father and mothers' relatives, and the correct breastfeeding positions were taught orally. In addition, a pamphlet containing breastfeeding training, prevalent problems related to this period, and misconceptions about breastfeeding will be given to the mothers. On average, each training will last 30 minutes. In each home visit, they will be asked about the continuation of exclusive breastfeeding by that time so that the treatment is intervened in the case that exclusive breastfeeding is stopped.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406073034N14**

Registration date: **2015-12-24, 1394/10/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-24, 1394/10/03

Registrant information

Name

Mansoureh Jamshidimanesh

Name of organization / entity

Iran University Faculty of Nursing & Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 21 4365 1811

Email address

delshad2@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, International campus, Iran
University of Medical Science

Expected recruitment start date

2015-12-21, 1394/09/30

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of home visit on mothers perceived social support
and continue exclusive breastfeeding

Public title

Effect of home visit on mothers perceived social support
and continue exclusive breastfeeding

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria : Iranian mothers; lack of chronic
physical and mental diseases in mothers as a reason for
the cessation of inclusive breastfeeding; mothers who
are not working at health centers; mothers with 3 to 5-
day-old infants who use breastfed; lack of illness in infant
asa reason for the cessation of exclusive breastfeeding.
Exclusion criteria : the children and mothers who become
illness during the study; mothers who use lactation pump
to feed their infants

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee in Iran University of Medical
Sciences

Street address

Hemmat Highway

City

Tehran

Postal code

Approval date

2015-11-08, 1394/08/17

Ethics committee reference number

IR.IUMS.REC.1394.9213593204

Health conditions studied

1

Description of health condition studied

exclusive breastfeeding

ICD-10 code

P92.5

ICD-10 code description

Neonatal difficulty in feeding at breast

2

Description of health condition studied

perceived social support of mothers

ICD-10 code

z59.7

ICD-10 code description

Insufficient social insurance and welfare support

Primary outcomes

1

Description

perceived social support of mothers

Timepoint

before intervention and the end of 6 month of birth

Method of measurement

questionnaire

2

Description

exclusive breastfeeding

Timepoint

at the end of 1 to 6 months of birth

Method of measurement

questionnaire

Secondary outcomes

1

Description

fathers attitude regarding breastfeeding

Timepoint

at the end of 6 month of birth

Method of measurement

questionnaire

2**Description**

The number of times breastfeeding

Timepoint

at the end of 1 to 6 months of birth

Method of measurement

by asking of mothers

Intervention groups**1****Description**

Intervention group: At the end of 1to 6 months, 6 home visit will be done. The educations of exclusive breastfeeding via lecture and pamphlet with mother's baby and fathers and people that are important for mother .

Category

Other

2**Description**

conrtol group: standard education in Health Centers

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amirabad

Full name of responsible person

Zainab Bayati

Street address**City**

Boukan

2**Recruitment center****Name of recruitment center**

Koltappeh

Full name of responsible person

Zainab Bayati

Street address**City**

Boukan

3**Recruitment center****Name of recruitment center**

Ali Abad

Full name of responsible person

Zainab Bayati

Street address**City**

Boukan

4**Recruitment center****Name of recruitment center**

Center No 4

Full name of responsible person

Zainab Bayati

Street address

Eslam Abad Street

City

Boukan

5**Recruitment center****Name of recruitment center**

Center No 5

Full name of responsible person

Zainab Bayati

Street address

Ostad Himen Street

City

Boukan

6**Recruitment center****Name of recruitment center**

Center No 6

Full name of responsible person

Zainab Bayati

Street address

Kordestan Bolv

City

Boukan

7**Recruitment center****Name of recruitment center**

Center No 7

Full name of responsible person

Zainab Bayati

Street address

East Molavi Street

City

Boukan

8**Recruitment center****Name of recruitment center**

Center No 8

Full name of responsible person

Zainab Bayati

Street address

Shohada Street
City
Boukan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, school of Nursing and
Midwifery, Iran University of Medical Scienc

Full name of responsible person

Mansoureh Jamshidimanesh

Street address

Hemmat 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, school of Nursing and
Midwifery, Iran University of Medical Scienc

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

Iran University of Medical Scienc

Full name of responsible person

Mansoureh Jamshidimanesh

Position

reproductive health candidate

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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Full name of responsible person

Position

Other areas of specialty/work

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City

Postal code

Phone

00

Fax

Email

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Web page address

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