Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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
exclussive 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
questionaire

2

Description
exclussive 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
questionaire

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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Person responsible for updating data

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Full name of responsible person

Position

Other areas of specialty/work

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City

Postal code

Phone

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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