

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of post-natal counseling on breastfeeding problems and exclusive breastfeeding

Protocol summary

Study aim

Educational-Counseling

Design

A randomized controlled clinical trial

Settings and conduct

one hundred and seventy eligible mothers were selected on the first day of delivery after obtaining written consent. Four groups were assigned to intervention group and 85 to control group. For intervention group, first consultation on days 3-5 and subsequent consultation on 15-15 days after delivery to advise on proper breastfeeding and how to prevent breastfeeding problems for mothers (including nipple fissure, mastitis, ...) These cases were handled by trained midwifery and nursing experts on how to deal with it and exclusively breastfeed. The mothers received telephone instruction for at least 20 minutes and the mothers' questions were answered. Subsequent counseling was performed on days 15-15 postpartum. The provider's telephone number was provided to the mothers to allow access in case of problems or questions. Both groups could receive routine care from the health centers. Outcomes were assessed on day 60 postpartum using a checklist and a questionnaire.

Participants/Inclusion and exclusion criteria

Iranian nationality; No underlying diseases; Existential singleton fetuses with normal birth weight and without congenital anomalies; Non-use of narcotic agent and drugs that are contraindicated in lactation

Intervention groups

Intervention group: receive telephone counseling in addition to routine care on days 3-5 and 13-15 postpartum. Control group: receive routine health care.

Main outcome variables

Problems of breastfeeding and exclusive breastfeeding (infant formula without any supplements except vitamins, minerals and medications)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190718044259N1**

Registration date: **2019-10-08, 1398/07/16**

Registration timing: **retrospective**

Last update: **2019-10-08, 1398/07/16**

Update count: **0**

Registration date

2019-10-08, 1398/07/16

Registrant information

Name

Parastoo Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4422 2139

Email address

mahyarmoraveji91@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-01, 1396/06/10

Expected recruitment end date

2017-10-07, 1396/07/15

Actual recruitment start date

2017-09-01, 1396/06/10

Actual recruitment end date

2017-10-07, 1396/07/15

Trial completion date

2017-12-06, 1396/09/15

Scientific title

The effect of post-natal counseling on breastfeeding problems and exclusive breastfeeding

Public title

The effect of support through telephone counseling on breastfeeding problems and exclusive breastfeeding

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian nationality No underlying disease The singleton fetuses with normal birth weight and without congenital anomalies No drugs and drugs that are contraindicated in lactation Residence in the area Phone access No problem with speech and hearing

Exclusion criteria:

Infant death for any reason during the study Maternal or neonatal illnesses that lead to discontinuation of breastfeeding by a specialist doctor

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **85**

Actual sample size reached: **77**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization was used for randomization. Sample allocation in the study was based on a random sequence provided by the statistics consultant (using statistical software). The sequence used was quadruple blocks.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

The content of telephone counseling is based on ministerial instructions, the WHO and other sources and each telephone consultation is divided into two parts: In the first part, the counselor questions the mother during the week and notes on the checklist The existing problem of consultation is to the extent that it is in line with the objectives of the research. The second part is dedicated advice on supporting exclusive breastfeeding, consulting with mothers and referrals to specialist centers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Sabzevar University of Medical Sciences

Street address

Tohidshahr Blvd

City

Sabzevar

Province

Razavi Khorasan

Postal code

9613873136

Approval date

2017-08-28, 1396/06/06

Ethics committee reference number

IR.MEDSAB.REC.1396.60

Health conditions studied

1

Description of health condition studied

Exclusive breastfeeding

ICD-10 code

P92

ICD-10 code description

Feeding problems of newborn

2

Description of health condition studied

breastfeeding problems

ICD-10 code

O91

ICD-10 code description

Infections of breast associated with pregnancy, the puerperium and lactation

3

Description of health condition studied

Cracked nipple

ICD-10 code

O92.1

ICD-10 code description

Cracked nipple associated with pregnancy, the puerperium, and lactation

Primary outcomes

1

Description

Mastitis

Timepoint

13-15 days after childbirth

Method of measurement

Checklist, Ask the mother

2

Description

cracked nipple

Timepoint

13-15 days after childbirth

Method of measurement

Checklist, Ask the mother

3

Description

Exclusive breastfeeding In the last 24 hours(Human milk intake by infant without any supplements (water, fruit, non-human milk and food) except vitamins, minerals and medicines).

Timepoint

60 days after childbirth

Method of measurement

Checklist, Ask the mother

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive regular telephone counseling. The first phone call will be made within the first 48 hours after hospital discharge (day 3 to 5 after delivery). According to WHO studies and information, these days are the most important time, and mothers have the least access to health centers and hospitals because of their problems and child support. The second consultation is at 13-15 days postpartum. It takes an average of 20 minutes depending on the individual's needs. Each telephone consultation has two parts: In the first section, the counselor questions the mother during the week and notes in the checklist, based on the existing problem to the extent that it is in line with the research objectives. The second part is dedicated advice on supporting exclusive breastfeeding. Counseling is provided by a midwifery graduate student with specialized short-term training in postpartum counseling. The telephone is also provided to mothers so that they can contact the counselor if needed. Both groups will receive routine postpartum education and care (usually three times in 42-60 days) from the delivery site and the health care centers covered on a routine basis.

Category

Prevention

2

Description

Control group: Care can be received from health centers according to the protocol of the Ministry of Health.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahidan Mobini Hospital of Sabzevar

Full name of responsible person

Gholamabbas Kafi

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Fereshteh Ghorat

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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

Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Parastoo Amiri
Position
Consultant
Latest degree
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5

Person responsible for scientific inquiries

Contact

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5

Person responsible for updating data

Contact

Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Kazem Hassanpour
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<http://www.medsab.ac.ir/index.aspx?siteid=1&fkeyid=&siteid=1&pageid=9380>

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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available