Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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Iran (Islamic Republic of)
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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
Kashefi Street
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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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Web page address
http://www.medsab.ac.ir/index.aspx?siteid=1&siteid=1&fkeyid=&siteid=1&fkeyid=&siteid=1&pageid=2085
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

Specialist

Other areas of specialty/work

Public Health/Community Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Kazem Hassanpour

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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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