

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial comparing the effect of peer counseling and routine training delivered by health centers on breastfeeding behavior in primipara mothers

Protocol summary

Study aim

To determine the effect of peer counseling and routine training delivered by health centers on breastfeeding behavior of primipara mothers

Design

This study is a randomized, controlled field trial with parallel groups without blindness.

Settings and conduct

The study was performed in health centers of Birjand. A total of 80 mothers with inclusion criteria were selected through multi-stage random sampling among mothers referring to Birjand health centers. Also, 10 other mothers with traits maximally similar to those of the target group were identified as the peer support group from among those referring to each region. The intervention group received two 3-hour sessions of training by peers. The controls received the routine training of the health center.

Participants/Inclusion and exclusion criteria

Main inclusion criteria: willingness to collaborate in the study and the first pregnancy or childbirth of the mother. Main exclusion criteria: disabling disease and breast problems in the mother and presence of prohibitions for breastfeeding.

Intervention groups

Intervention group: the group members were trained by the peer counselors during two 3-hour sessions. The contents of the sessions included anatomy, principles and skills of breastfeeding, and proper breastfeeding techniques, etc. according to the guidelines and syllabuses provided by the Ministry of Health and the World Health Organization. The mothers could also contact the counselor at any time via telephone or in person. Control group: they received the routine training of the health centers in person.

Main outcome variables

Breast feeding behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170316033099N4**

Registration date: **2018-12-01, 1397/09/10**

Registration timing: **retrospective**

Last update: **2018-12-01, 1397/09/10**

Update count: **0**

Registration date

2018-12-01, 1397/09/10

Registrant information

Name

Mohammad Bagher Roozgar

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3239 5680

Email address

roozgar@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-13, 1396/11/24

Expected recruitment end date

2018-08-08, 1397/05/17

Actual recruitment start date

2018-02-13, 1396/11/24

Actual recruitment end date

2018-08-08, 1397/05/17

Trial completion date

Scientific title

Clinical trial comparing the effect of peer counseling and routine training delivered by health centers on breastfeeding behavior in primipara mothers

Public title

Effect of peer counseling on breastfeeding behavior

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to collaborate in the study Residence in Birjand Having reading and writing literacy The newborn being a single child The first pregnancy or childbirth of the mother

Exclusion criteria:

Disabling disease and breast problems in the mother Congenital anomalies and oral abnormalities in the newborn Presence of prohibitions for breastfeeding Hospitalization of the newborn

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 80 mothers with inclusion criteria were selected through multi-stage random sampling from among mothers referring to Birjand health centers. To select the samples, the city of Birjand was classified into northern and southern regions. From each region, two health bases were randomly selected from the bases covered by the health centers of that area, and one base was placed in the intervention group and one base in the control group. Then, in each base, based on the Integrated Health System, the list of eligible primipara women was extracted, and 20 individuals were subsequently randomly selected from each base. Accordingly, 40 women were in the intervention group and 40 women in the control group.

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

Ethics Committee of Birjand University of Medical Sciences

Street address

Ghaffari Ave.

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2018-02-12, 1396/11/23

Ethics committee reference number

IR.BUMS.REC.1396.317

Health conditions studied

1

Description of health condition studied

Breastfeeding behavior

ICD-10 code

P92.9

ICD-10 code description

Feeding problem of newborn, unspecified

Primary outcomes

1

Description

Breastfeeding behavior

Timepoint

Before intervention; immediately after the intervention; at the end of the first, second and third months after intervention

Method of measurement

B-R-E-A-S-T-Feeding Observation Form

Secondary outcomes

1

Description

Complementary milk consumption

Timepoint

Immediately after the intervention, at the end of the first, second and third months after intervention

Method of measurement

Asking the mother

Intervention groups

1

Description

Intervention group (Peer counseling): the intervention group completed B-R-E-A-S-T-Feeding Observation Form before intervention. They were trained and supported by the peer counselors during two 3-hour sessions. The contents of the sessions included anatomy, principles and skills of breastfeeding, problems and incorrect beliefs about breastfeeding and infant nutrition, and proper breastfeeding techniques, etc. according to the guidelines and syllabuses provided by the Ministry of Health and the World Health Organization. The mothers could contact the sponsor at any time, via telephone or in person, and raise problems concerning their baby's breastfeeding and nutrition. The counselor also had a weekly phone call with mothers to encourage them to continue and perform proper breastfeeding skills. Immediately after the intervention, at the end of the first, second and third months after intervention, the standard B-R-E-A-S-T-Feeding Observation Form was completed.

Category

Behavior

2

Description

Control group (Routine training): the control group completed B-R-E-A-S-T-Feeding Observation Form before intervention. They received the routine face-to-face training at the health bases at the time of referral. Immediately after the intervention, at the end of the first, second and third months after intervention, the standard B-R-E-A-S-T-Feeding Observation Form was completed.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghadir Healthcare Center

Full name of responsible person

Nasimeh Azimi Tabas

Street address

Ghadir Boulevard

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 56 3241 4486

Email

na.azimi1395@gmail.com

2

Recruitment center

Name of recruitment center

Reja'i Healthcare Center

Full name of responsible person

Nasimeh Azimi Tabas

Street address

Kargaran Ave.

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 56 3231 6815

Email

na.azimi1395@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Tooba Kazemi

Street address

Ghaffari Ave.

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 56 3238 1200

Email

drtooba.kazemi@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Nasimeh Azimi Tabas
Position
MSc Student of Nursing
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Meghdad Ave.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3239 1514
Email
na.azimi1395@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Dr. Ahmad Nasiri
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Ghaffari Ave.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3239 1415
Email
A.nasiri@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Birjand University of Medical Sciences

Full name of responsible person
Mohammad Bagher Roozgar
Position
Translator
Latest degree
Master
Other areas of specialty/work
Others
Street address
Ghaffari Ave.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3239 5641
Email
hadirooz@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Deidentified Individual Participant Data Set
When the data will become available and for how long
when the extracted paper from the project will be published and for 6 months
To whom data/document is available
all readers of the paper
Under which criteria data/document could be used
research purposes
From where data/document is obtainable
personal correspondence with the corresponding author
What processes are involved for a request to access data/document
email
Comments