

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Impact of counseling on motivational interviewing approach on exclusive breastfeeding in nulliparous women

Protocol summary

Study aim

Determining the effect of counseling on motivational interviewing approach on exclusive breastfeeding in nulliparous women in Mashhad health centers in 1397

Design

Clinical trials ,Without blindness , randomized.

Settings and conduct

At first, five centers of health centers in Mashhad, Center No. 1 and No. 3 were selected randomly. Then, based on the population coverage and having the right place for consultation, four urban bases were selected. Random assignment of groups using closed envelopes. To prevent the publication or imitation of interventions, 4 urban bases will be placed in two different groups (2 urban bases in the intervention group and 2 in the control group).

Participants/Inclusion and exclusion criteria

Inclusion criteria: willingness to participate in the study, No hearing and speech problems, age 18-35 years, gestational age between 34 weeks and 36 weeks, Be single, no pregnancy, no history of surgery or anatomical impairment of breast, Be nulliparous , no specific drug use, no specific disease. Exclusion criteria: a newborn baby is transferred to the intensive care unit, the baby is infected due to problems leading to impairment of breastfeeding, absenteeism More than one meeting in counseling sessions, failure to complete a daily infant feeding report for 11 days in the follow-up period, The baby's birth weight is below 2500.

Intervention groups

The intervention consists of four group counseling sessions for 75 minutes based on the motivational interview structure. The control group receives the routine care from the health center.

Main outcome variables

Average score for exclusive breastfeeding in the neonatal period

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180731040651N1**

Registration date: **2019-07-11, 1398/04/20**

Registration timing: **retrospective**

Last update: **2019-07-11, 1398/04/20**

Update count: **0**

Registration date

2019-07-11, 1398/04/20

Registrant information

Name

Faeze Aliasghary

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7624 2196

Email address

aliasgharif951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of counseling on motivational interviewing approach on exclusive breastfeeding in nulliparous women

Public title

Effect of training on breastfeeding in primipara mothers

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Iranian race Residence in Mashhad Access to phone Minimal fifth degree of elementary education Staff not employed in the hospital No smoking and alcohol There are no audible and verbal problems that prevent communication with the researcher Age between 18 and 35 years old Gestational age between 34 weeks 36 weeks In the last 6 months have not had severe mental problems singleton No high risk pregnancy There is no history of breast surgery or anatomical defects in the breast The absence of known embryonic anomalies in ultrasound The maternal BMI is between 19/8 and 26 Be nulliparous. Desire to cooperate No specific drug intake No specific disease

Exclusion criteria:

The next baby is transferred to the intensive care unit Occurrence of postpartum disaster Occurrence of postpartum medical problems The baby is infected with problems that lead to impairment in breastfeeding A visit has not been done in the first week or the fourth week Missing more than one meeting in counseling sessions Mother suffered from postpartum depression Failure to complete the daily infant feeding report for 11 days during the follow-up period The baby's birth weight is under 2500 The age at birth is below 37 weeks The Apgar score is below 7

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization.By lottery

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 Mashhad University of Medical Sciences and Health Services

Street address

Deputy of Research and Technology University, Mashhad University of Medical Sciences, Opposite University Street 18,University Street

City

Mashhad

Province

Razavi Khorasan

Postal code

05138430249

Approval date

2018-07-03, 1397/04/12

Ethics committee reference number

IR.MUMS.NURSE.REC.1397.001

Health conditions studied**1****Description of health condition studied**

Exclusive Breastfeeding during neonatal period

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The rate of exclusive breastfeeding in the neonatal period

Timepoint

Determine the amount of exclusive breastfeeding at the end of a 4 week infant

Method of measurement

Daily Feeder Checklist

Secondary outcomes**1****Description**

Attitude towards exclusive breastfeeding

Timepoint

Before intervention, four weeks after childbirth

Method of measurement

The score of the questionnaire of Attitude towards exclusive breastfeeding

2**Description**

The frequency of exclusive breastfeeding plan

Timepoint

Before intervention, four weeks after childbirth

Method of measurement

The score obtained from the exclusive breastfeeding questionnaire intention

3

Description

Self-efficacy of exclusive breastfeeding

Timepoint

Four weeks after childbirth

Method of measurement

Breastfeeding self-efficacy questionnaire.

Intervention groups

1

Description

Intervention group: Four groups of motivational interviewing counseling sessions will be held in the 35,36,37,38 weeks of pregnancy for 75 minutes per session based on the structure developed by the researcher and approved by a professor of psychology.

Category

Behavior

2

Description

Control group: The routine consultation on exclusive breastfeeding will be provided by midwives at health centers.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center No. 3 of Mashhad

Full name of responsible person

Brattali Arab Nejad

Street address

in front of the payam 6, Khayyam Boulevard, 8 Ershad Blvd.

City

Mashhad

Province

Razavi Khorasan

Postal code

9185837715

Phone

+98 51 3763 4007

Email

presidentoffice@mums.ac.ir

2

Recruitment center

Name of recruitment center

Health Center Number one

Full name of responsible person

Dr. Naser Amini

Street address

Health center number one in Mashhad city, between Vakil Abad 66 and 68, Vakil Abad Boulevard

City

Mashhad

Province

Razavi Khorasan

Postal code

9179793945

Phone

+98 51 3501 8011

Email

presidentoffice@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Darabi Mahbub

Street address

Presidential Building of Khorasan Razavi University of Medical Sciences and Health Services, Quraishi Building, University of Ave.

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Mashhad

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91357-345

Phone

+98 51 3007 3841

Email

presidentoffice@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Faeze Aliasghari

Position

Masters student of Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery of Mashhad, Doctora
Crossroads, University Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

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Email

Aliasgharif951@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

sedighe yusefzade

Position

Academic staff of Mashhad University of Medical
Sciences

Latest degree

Master

Other areas of specialty/work

Midwifery

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City

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Province

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Email

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

sedighe yusefzade

Position

Academic staff of Mashhad University of Medical
Sciences

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery of Mashhad, Doctora
Crossroads, University Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

yousefzadehs@mums.ac.ir

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

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data can be shared with the original
outcome

When the data will become available and for how long

6 months after registering the results

To whom data/document is available

All researchers

Under which criteria data/document could be used

All lactating women

From where data/document is obtainable

Email faliasghary@gmail.com and the library of the
Mashhad Nursing and Midwifery Faculty to the University
of Mashhad address.

What processes are involved for a request to access data/document

First, an email is requested and can be submitted to the
Nursing Faculty Library of Mashhad in case of non-
response within a maximum of one week.

Comments