

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Investigating the effect of breastfeeding counseling based on the information - motivation - behavior skills (IMB) model on the some of maternal and newborn's health indicators among referees to the breastfeeding counseling center

Protocol summary

Study aim

the effect of breastfeeding counseling based on the information , motivation , behavior skills (IMB) model on the some of maternal and newborn's health indicators

Design

Clinical trial work with control group, with parallel groups, without blinding, randomized, on 62 mothers and their newborns, Excel software was used for randomization

Settings and conduct

Available sampling, mothers and their babies, infancy period, Bahman 22 centre

Participants/Inclusion and exclusion criteria

Infancy period mother hasn't prohibite from breastfeeding mother hasn't an untreated psychiatric mother doesn't take medicine that prohibits breastfeeding mother should be Iranian / Afghan people who speak Persian Stop breastfeeding no cooperation in filling the questionnaires and checking the study indicators after intervention at 2, 4 and 6 months mother uses a particular diet/exercise in order to decrease weight Diseases disrupt breastfeeding , such as Sheehan's syndrome

Intervention groups

Intervention group: 4 training sessions based on the behavioral motivation information model. Reviews at 2, 4 and 6 months Routine group: a routine training session of the counseling center and face-to-face examinations like the intervention group

Main outcome variables

breastfeeding observation, Latch, weight of the baby on the first day, 2, 4 and 6 months, BMI, blood pressure, and postpartum depression, Infant behavior (only at 6 months)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170611034452N15**

Registration date: **2023-04-28, 1402/02/08**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-28, 1402/02/08**

Update count: **0**

Registration date

2023-04-28, 1402/02/08

Registrant information

Name

Atefeh Ahmadi

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5205

Email address

a.ahmadi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2025-04-21, 1404/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of breastfeeding counseling based on the information – motivation – behavior skills (IMB) model on the some of maternal and newborn's health indicators among referees to the breastfeeding counseling center

Public title

Investigating the effect of breastfeeding counseling on the quality and continuity of breastfeeding and the health of mothers and babies

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Infancy period mother hasn't prohibition for breastfeeding mother hasn't an untreated psychiatric mother doesn't take medicine that prohibit breastfeeding mother should be Iranian / Afgan people who spease persian

Exclusion criteria:

Stopping exclusive breastfeeding and then , starting bottle feeding Non cooperation in comple the questionnaires and checke the study indicators after intervention at 2 , 4 and 6 months If mother use a special diet / exercise in order to decrease weight but it doesn't cause decrease breastfeeding, it isnot important Diseases disrupt on breastfeeding , such as Sheehan's syndrome

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Mothers and their babies who are eligible will continue to be selected by available sampling method until reaching the sample size (at least 21 people in each group). Using the software (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>) People are placed in two groups of routine care and intervention with simple randomization method (double blocks).

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**

Research Ethics Committees of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Medical University campus. Haft. Bagh Highway, Kerman ,Iran Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2023-04-15, 1402/01/26

Ethics committee reference number

IR.KMU.REC.1402.012

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

Breastfeeding counseling in mothers with breastfeeding problems

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

Breastfeeding counseling based on the IMB model

Timepoint

before the intervention and after the intervention at 2, 4 and 6 months

Method of measurement

WHO breastfeeding observation form checklist, Latch questionnaire

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

Newborn weight

Timepoint

The first day of visit, then at 2, 4 and 6 months

Method of measurement

It is measured using a digital flat scale (874 seca, Germany).

Intervention groups

1

Description

Intervention group: Breastfeeding counseling based on correct breastfeeding teaching based on the model of information, motivation, and behavior to improve some maternal and child health indicators, which is the first face-to-face session immediately after sampling. In the second session if the problem is not resolved the mother will visit face to face the next day. If the mother does not come, the consultant will make a phone call on the 1st-3rd day via WhatsApp or Rubika. the consultant Coordinates with the mother to contact WhatsApp or Rubika. If not possible, a phone call will be made. Follow-ups determin on the 7th, 14th and 21st days from the time of the mother's visit (the second day after giving birth does not include, for example a mother who visited on the 16th day after giving birth, the follow-up date of the mother is determined 7 days later from the time of the visit). the first counseling session (referral day): 1.to state goals and rules 2.to define latch and position trainingthe importance of their correct performance in maternal and newborn outcomes. to state the difference of maternal and newborn outcomes in correct and incorrect breastfeeding. task: performing correct breastfeeding (to the mother). if The mother's breastfeeding problem does not solve, she can come back the next day or she can give number to call him. If person does not refer or call, counselor call with him on day 1-3. The second counselling session of day 1 to 3: (face to face or by phone) if mother come back counselor revision remaining problem and then following step will be performed and then the following steps will be performed:1. check the correctness of the mother's breastfeeding 2.state the process of correct breastfeeding and its continue based on the relationship between information and motivation and breastfeeding skills3. mention the benefits of proper breastfeeding in the child (based on the indicators examined in this study, if the mother does not come back, counselor will call him). Follow-up on day 7: (phone call)1.check the correctness of mother's breastfeeding2.state maternal benefits of correct breastfeeding (based on the indicators examined in this study). Follow-up on day 14: (phone call) 1.check the correctness of mother's breastfeeding2. motivate the mother to continue correct breastfeeding. Follow-up on day 21: (phone call)1. check the correctness of mother's breastfeeding2.creating self-care and guidance to remove personal, family and environmental obstacles to proper breastfeeding. The third counseling session, the end of the third month: (telephone call)check the correctness of mother's breastfeeding2.creat self-efficacy and guidance to remove personal, family and environmental obstacles to correct breastfeeding. The fourth counseling session, the end of the fifth month: (telephone call)1.check the correctness of the mother's breastfeeding2.creating self-efficacy and guidance to remove personal, family and environmental obstacles to proper breastfeeding. The third counseling session, the end of the third month:

(telephone call)1. check the correctness of mother's breastfeeding2. creat self-efficacy and guidance to remove personal, family and environmental obstacles to correct breastfeeding. The fourth counseling session, the end of the fifth month: (telephone call)1.check the correctness of the mother's breastfeeding2. creat self-efficacy and guidance to remove personal, family and environmental obstacles to correct breastfeeding.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Kerman City Referral Center (22 Bahman Center)

Full name of responsible person

Masoume Abdullahi Apoorvari

Street address

22 Bahman comprehensive health service center, after Seyed Jamaluddin Asadabadi St

City

Kerman

Province

Kerman

Postal code

7616745854

Phone

+98 34 3334 2180

Fax

Email

maa13561454@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Reza Malekpour Afshar

Street address

Kerman University of Medical Sciences, Medical University campus. Haft. Bagh Highway,Kerman ,Iran Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5700

Email

intdep2@gmail.com

Web page address

<http://vresearch.kmu.ac.ir/fa>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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**

Kerman University of Medical Sciences

Full name of responsible person

Atefeh Ahmadi

Position

associate prof

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5220

Email

a.ahmadi@kmu.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Atefeh Ahmadi

Position

associate prof

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5220

Email

a.ahmadi@kmu.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Atefeh Ahmadi

Position

associate

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5220

Email

a.ahmadi@kmu.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

all collected deidentified IPD

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

with previous agreement with the corresponding author

From where data/document is obtainable

email address

What processes are involved for a request to access

data/document

email address

Comments