

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The effect of family-oriented counseling on breastfeeding continuity in women with distractions caused by media technologies

Protocol summary

Continuity of breastfeeding, Technology distraction

Study aim

Determining the effect of family-centered counseling on breastfeeding continuity in women with media technology distractions

Design

Phase III of a randomized controlled trial, with the parallel group, will be conducted on 120 lactating women. We do not have blinding. Eligible women will be selected in the convenience method during regular postpartum care visits, and then will be allocated into two groups using the random block with the size of 4 blocks. The random blocks will be selected using the randomizer software.

Settings and conduct

Lactating women who refer to Zanzan Comprehensive Health Center within the first 42 days after delivery will be randomly assigned into two groups. We do not have blinding. The intervention will be family-oriented counselling in three face-to-face meetings with the participation of at least one family member.

Participants/Inclusion and exclusion criteria

Inclusion criteria Lactating mothers who are two weeks to 42 days postpartum, living with a partner, exclusive breastfeeding or combination feeding, having at least one case of media-induced distraction based on the mother distraction questionnaire. Exclusion criteria are bottle feeding and Prohibition of breastfeeding

Intervention groups

The intervention group will receive family-centred counselling in three face-to-face sessions with the participation of at least one family member, preferably her spouse. The duration of the sessions is between 45 to 60 minutes and the intervals of one week. Content of sessions includes breastfeeding training based on national guidelines, lifestyle changes, and strategies to reduce distractions during baby care and breastfeeding. The control group will receive routine care including breastfeeding education based on national guidelines.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150731023423N21**

Registration date: **2022-08-09, 1401/05/18**

Registration timing: **prospective**

Last update: **2022-08-09, 1401/05/18**

Update count: **0**

Registration date

2022-08-09, 1401/05/18

Registrant information

Name

Azam Maleki

Name of organization / entity

Zanzan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3345 4264

Email address

malekia@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-24, 1401/06/02

Expected recruitment end date

2023-01-30, 1401/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family-oriented counseling on breastfeeding continuity in women with distractions caused by media technologies

Public title

The effect of family-oriented counseling on breastfeeding continuity in women with distractions caused by media technologies

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having at least one case of media-induced distraction based on the mother distraction questionnaire
Breastfeeding mothers who are two weeks to 42 days postpartum. Living with a spouse Exclusive breastfeeding or combination feeding

Exclusion criteria:

Bottle feeding Contraindications to breastfeeding

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

One hundred and twenty eligible women were selected during routine postpartum care visits using the convenience sampling method and then they will be assigned to two groups using a random blocking method with block sizes of four. In this way, six blocks will be assigned to group A (intervention) and group B (control). Then, the number of blocks will be selected using Random Number Table.

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 Zanajn University of Medical Sciences

Street address

Zanjan University of Medical Sciences Headquarters, the beginning of the Islamic Republic Blvd, Azadi Square, Zanjan. Iran

City

Zanjan

Province

Zanjan

Postal code

۴۵۱۵۶۱۳۱۹۱

Approval date

2022-06-21, 1401/03/31

Ethics committee reference number

IR.ZUMS.REC.1401.136

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

Breastfeeding continuation

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Distraction media technologies

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

Breastfeeding continuation

Timepoint

Before intervention, Every month up to 4 months after the intervention

Method of measurement

Nutrition Classification System of the World Health Organization to assess the continuity of breastfeeding

2**Description**

Media technology distraction

Timepoint

Before intervention, Every month up to 4 months after the intervention

Method of measurement

Maternal Distraction Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will be received family-oriented counselling in three face-to-face sessions with the participation of at least one family member, preferably their spouse. The duration of the meetings is between 45 and 60 minutes and the holding intervals are considered to be one week. The content of the sessions includes breastfeeding education based on national guidelines, lifestyle changes and strategies to reduce distractions during baby care and breastfeeding. Including making a list of distractions during breastfeeding, practising mind management strategies to reduce distractions while breastfeeding or taking care of the child, practising not using mobile phones and other media technologies, and a financial agreement as a fine. For a more accurate assessment, daily notebooks will be provided to mothers to record breastfeeding patterns and counselling assignments.

Category

Lifestyle

2

Description

The control group will be received routine care including breastfeeding education based on national guidelines.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

The comprehensive health centers of Zanjan.

Full name of responsible person

Elaheh Arezi Tekantapeh

Street address

Zanjan Health Centers

City

Zanjan

Province

Zanjan

Postal code

5991769164

Phone

+98 44 4552 6622

Email

arezi.eli@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Samad Nadri

Street address

Zanjan University of Medical Sciences, Islamic Republic Street, Azadi Boulevard, Zanjan

City

Zanjan

Province

Zanjan

Postal code

4515613191

Phone

+98 24 3524 2075

Email

Research@zums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Elahe Arezi Takantappe

Position

Master student of counseling in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Zanjan University of Medical Sciences, Gavazang Road, Zanjan

City

Zanjan

Province

Zanjan

Postal code

4515613191

Phone

+98 44 4552 6622

Email

arezi.eli@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Maleki Azam

Position

PhD in Maternal and Child Health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Zanjan University of Medical Sciences, Gavazang Road, Zanjan

City

Zanjan

Province

Zanjan

Postal code

4515613191

Phone

+9824334206519

Email

Malekia@zums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Maleki Azam

Position

PhD in Maternal and Child Health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Zanjan University of Medical Sciences, Gavazang Road, Zanjan

City

Zanjan

Province

Zanjan

Postal code

4515613191

Phone

+9824334206519

Email

Malekia@zums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available