

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparison of the effectiveness of intermittent counseling approach with the continuous counseling method in improving breastfeeding self-efficacy and continuity among women infected with covid-19

#### Protocol summary

##### Study aim

Comparison of the effectiveness of intermittent counseling approach with the continuous counseling method in improving breastfeeding self-efficacy and continuity among women infected with covid-19

##### Design

The study will be a quasi-experimental study with two intervention groups. The participant will be selected by the convenience sampling method. The sample size will be 46 people.

##### Settings and conduct

The study setting will be Ayatollah Mousavi Zanzan. The first intervention group, continues breastfeeding counseling will be received daily and the second intervention group intermittent breastfeeding counseling will be received weekly for up to four weeks by phone and Whatsapp. The self-efficacy of breastfeeding will be measured using the Dennis Short Form Questionnaire before, four weeks, and 4 months after delivery, the continuation of breastfeeding will be determined monthly up to 4 months after delivery. We do not have blinding.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Initiation breastfeeding of the baby immediately after delivery, A positive Covid-19 PCR test and Stability of the mother's health and her baby  
Exclusion criteria: Childbirth less than 34 weeks of gestation, contraindications to breastfeeding, and the Need special care in mother and her baby

##### Intervention groups

The first intervention group: continuous breastfeeding counseling will be received based on an individual approach, daily for 14 days, and the second intervention group: intermittent Breastfeeding counseling will be received weekly up to four weeks by phone and WhatsApp. The first counseling session in both groups will be held by face-to-face approach. Then continued during the hospitalization period and after discharge,

according to the mentioned protocols. We do not have a control group in this study.

##### Main outcome variables

Breastfeeding self-efficacy and continuity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150731023423N19**

Registration date: **2021-06-29, 1400/04/08**

Registration timing: **prospective**

Last update: **2021-06-29, 1400/04/08**

Update count: **0**

##### Registration date

2021-06-29, 1400/04/08

##### 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

2021-07-01, 1400/04/10

##### Expected recruitment end date

2021-11-01, 1400/08/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effectiveness of intermittent counseling approach with the continuous counseling method in improving breastfeeding self-efficacy and continuity among women infected with covid-19

**Public title**

Effectiveness of intermittent counseling approach on women infected with covid-19

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Initiation feeding of the baby immediately after delivery  
A positive Covid-19 PCR test  
Stability of general health of the mother and her baby

**Exclusion criteria:**

Childbirth less than 34 weeks of gestation  
Contraindications to breastfeeding  
The special care in mother and her baby

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **46**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Other

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Zanjan University of Medical Sciences

**Street address**

Zanjan Azadi Blvd. Zanjan University of Medical Sciences

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4515613191

**Approval date**

2021-05-26, 1400/03/05

**Ethics committee reference number**

IR.ZUMS.REC.1400.066

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

COVID-19

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19, virus identified

**Primary outcomes****1****Description**

Breastfeeding Self-efficacy

**Timepoint**

Before intervention, four weeks and four months after delivery

**Method of measurement**

Dennis Breastfeeding Self-Efficacy Questionnaire

**2****Description**

Breastfeeding continuity

**Timepoint**

Monthly up to 4 months after delivery

**Method of measurement**

Self-report

**Secondary outcomes**

empty

**Intervention groups****1****Description**

The first intervention group, breastfeeding counseling will be received daily for two weeks individually using telephone and virtual networks (WhatsApp). The content of counseling sessions is in accordance with the latest version of the breastfeeding guidelines in women with Covid 19 that published by the Ministry of Health of Iran and Includes mother and child rooming conditions - Compliance requirements during breastfeeding -

Psychological support - Common complaints related to breastfeeding

**Category**

Prevention

**2**

**Description**

The second Intervention group: breastfeeding counseling will be received weekly for four weeks individually using telephone and virtual networks (WhatsApp). The content of counseling sessions is in accordance with the latest version of the breastfeeding guidelines in women with Covid 19 that published by the Ministry of Health of Iran and Includes mother and child rooming conditions - Compliance requirements during breastfeeding - Psychological support - Common complaints related to breastfeeding

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ayatollah Mousavi Hospital in Zanjan

**Full name of responsible person**

Dr.Azam Maleki

**Street address**

Gavazang Road, Zanjan University of Medical Sciences, Zanjan, Iran

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4515613191

**Phone**

+98 24 3242 0651

**Email**

malekia@zums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr.Alireza Shogli

**Street address**

Gavazang Road, Zanjan University of Medical Sciences, Zanjan, Iran

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4515613191

**Phone**

**Email**

maryam.karimi.6098@gmail.com

**Grant name**

**Grant code / Reference number**

A-11-344-23

**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**

Maryam.Karimi

**Position**

Master Student of Counseling in Midwifery

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Gavazang Road, Zanjan University of Medical Sciences, Zanjan,Iran

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4515613191

**Phone**

+98 24 3341 0992

**Email**

maryam.karimi.6098@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Dr.Azam Maleki

**Position**

Associate professor in Maternal and Child Health

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

Gavazang Road, Zanjan University of Medical Sciences, Zanjan,Iran

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4515613191

**Phone**

+98 24 3342 0651

**Email**

malekia@zums.zc.ir

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

Zanjan University of Medical Sciences

**Full name of responsible person**

Azam Maleki

**Position**

Associate professor in Maternal and Child Health

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

Gavazang Road, Zanjan University of Medical Sciences, Zanjan,Iran

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4515613191

**Phone**

+98 24 3315 6140

**Email**

malkia@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**

Possibility of dissatisfaction of participants

**Study Protocol**

Undecided - It is not yet known if there will be 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