

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

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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

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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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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

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

Zanjan University of Medical Sciences

Full name of responsible person

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Position

Associate professor in Maternal and Child Health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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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