

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of counseling with a positivist approach on self-efficacy of unsuccessful breastfeeding mothers

Protocol summary

Study aim

Determining the effect of counseling with a positivist psychology on the self-efficacy of unsuccessful breastfeeding mothers

Design

A randomized controlled clinical trial with parallel groups will be performed on 46 patients.

Settings and conduct

The study population in the study will be selected from all pregnant mothers who failed in previous breastfeeding referring to comprehensive health centers in Zanjan.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Failure of the pregnant mother in previous breastfeeding; Multipar mothers; Single pregnancy; Pregnant mothers with a self-efficacy score between 33 and 76; Lack of anatomical problem in the breast such as nipple depression and fissure; Willingness to participate in the study; Tendency to breastfeed; Literacy; Internet access and Android phone. Criteria for non-admission: mother suffering from mental disorders; Incidence of stressful events (accidents, death of a loved one, separation from a spouse, bankruptcy, severe disputes, immigration) in the last 6 months; Complications of pregnancy or childbirth; Congenital anomalies in the previous infant; The previous infant was admitted to the neonatal intensive care unit.

Intervention groups

In the 32nd to 37th weeks of pregnancy, positive psychology interventions will be held in eight sessions of 70-90 minutes, virtually and individually, two days a week, and the control group will receive routine pregnancy care training.

Main outcome variables

Self-efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160521027994N9**

Registration date: **2021-09-30, 1400/07/08**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-30, 1400/07/08**

Update count: **0**

Registration date

2021-09-30, 1400/07/08

Registrant information

Name

Taraneh Emamgholi khooshehchin

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3314 8318

Email address

khoosheh@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-21, 1400/06/30

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling with a positivist approach on self-efficacy of unsuccessful breastfeeding mothers

Public title

The effect of counseling on breastfeeding self-efficacy

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Failure of the pregnant mother in previous breastfeeding
Multipar mothers Single pregnancy Pregnant mothers with a self-efficacy score between 33 and 76
Tendency to breastfeed the baby Lack of anatomical problem in the breast such as nipple depression and fissure
Willingness to participate in the study Literacy Internet access and Android phone

Exclusion criteria:

Mother suffering from mental disorder Incidence of stressful events (accidents, death of a loved one, separation from a spouse, bankruptcy, severe disputes, immigration) in the last 6 months
Complications of pregnancy or childbirth Congenital anomalies in the previous infant The previous infant was hospitalized in the neonatal intensive care unit

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, at first, the easy sampling method will be used, next individuals with inclusion criteria will be divided into two groups of intervention and control, by using random block division. In this way, in the beginning , by using four blocks, the arrangement of people next to each other in each block will be determined; Thereafter a number will be assigned to each block, and 12 blocks will be determined to provide the required number of samples. Then, the table of random numbers is going to be used, the sequence of using the blocks will be determined. The process of entry to each group in each block will be done by the arrangement of inside the block and the number of selected blocks ;The number of people in each group will be 23.

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 Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Azadi Square, Zanjan

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2021-07-24, 1400/05/02

Ethics committee reference number

IR.ZUMS.REC.1400.152

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

Self-efficacy in breastfeeding

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

Self-efficacy

Timepoint

Before the intervention, the last consultation session and two months after the end of the intervention

Method of measurement

Dennis Breastfeeding Self-Efficacy Questionnaire

Secondary outcomes

empty

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

Intervention group: Counseling with a positive psychology approach for the intervention group will be held twice a week for 8 sessions of 70-90 minutes, and at the end of each session, participants will be given homework.

Category

Other

2

Description

Control group: In the control group routine care will be performed. Positive psychological counseling sessions will be held for them if they wish the participants in the control group after the intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive urban health centers

Full name of responsible person

Parvaneh - Rezaie

Street address

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4513665758

Phone

+98 24 3344 4280

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Doctor Alireza Shoghli

Street address

Zanjan University of Medical Sciences, Azadi Square,
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shoghli@zums.ac.ir

Grant name

Thesis

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

Parvaneh - Rezaie

Position

Senior Counselling Student In Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School Of Nursing and Midwifery, Carmandan
Boulevard, Zanjan

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Taraneh Emamgoli Khooshehchin

Position

Faculty

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

Parvaneh - Rezaie

Position

Senior Counselling Student In Midwifery

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Other areas of specialty/work

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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

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

Title and more details about the data/document

The release schedule is not yet known

When the data will become available and for how long

The release schedule is not yet known

To whom data/document is available

The release schedule is not yet known

Under which criteria data/document could be used

The release schedule is not yet known

From where data/document is obtainable

The release schedule is not yet known

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

The release schedule is not yet known

Comments