

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of counseling with stress management approach on anxiety and distress and breastfeeding self-efficacy in Corona pandemic: a clinical randomized controlled trial

Protocol summary

Study aim

Determining the effect of counseling with stress management approach on anxiety and distress and self-efficacy of lactating women in corona pandemic

Design

A randomized clinical trial with two parallel arms will be performed on 64 lactating women (first and second deliveries) who have given birth in the last month. Participants using RAS software in blocks of 4 and 6 with a ratio of 1: 1 will be assigned to two groups and will be followed up 4 weeks after the intervention.

Settings and conduct

Sampling will be performed on lactating women (first and second delivery) who have given birth in the last month and their details are available in Tabriz health centers. Participants will be assigned to two groups by random blocking. Anxiety, postpartum distress and breastfeeding self-efficacy questionnaires will be completed by both groups before the intervention and 4 weeks after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: first and second delivery and lactation (delivery in a recent month) and anxiety score 43 to 53, no hospitalization of the child and no unsolvable breastfeeding problem

Intervention groups

In the intervention group, counseling will be done in 6 sessions of 60 to 90 minutes individually in the health center, during which techniques such as relaxation, diaphragmatic breathing, identification of negative thoughts and reconstruction of those thoughts by replacing logical thoughts, effective coping training and expression skills are used. For the control group, a counseling session on contraceptive methods will be held for an average of 60-90 minutes.

Main outcome variables

Comparison of Anxiety Score, Postpartum Distress, and

Breastfeeding Self-Efficacy 4 weeks after the intervention, the Spielberger Anxiety, Postpartum Distress, and Breastfeeding Self-efficacy questionnaires will be measured.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171007036615N6**

Registration date: **2021-09-15, 1400/06/24**

Registration timing: **prospective**

Last update: **2021-09-15, 1400/06/24**

Update count: **0**

Registration date

2021-09-15, 1400/06/24

Registrant information

Name

عصمت مهرابی

Name of organization / entity

دانشگاه علوم پزشکی تبریز

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-02, 1400/07/10

Expected recruitment end date

2022-01-30, 1400/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling with stress management approach on anxiety and distress and breastfeeding self-efficacy in Corona pandemic: a clinical randomized controlled trial

Public title

The effect of counseling with stress management approach on anxiety and distress and breastfeeding self-efficacy in Corona pandemic

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

First and second delivery and lactation (delivery in a recent month) Anxiety score 43 to 53 Having a contact number to follow Literacy

Exclusion criteria:

Uncertainty about being able to attend all counseling sessions The child is hospitalized Insoluble breastfeeding problem Achieve an anxiety score above 53 Distress score above the average of the total score

AgeFrom **18 years** old to **35 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **64****Randomization (investigator's opinion)**

Randomized

Randomization description

Participants will be assigned to the two groups receiving the intervention and control through simple random blocking using RAS software with 4 and 6 blocks with a ratio of 1: 1. The allocation type will be written on paper and numbered in a series of opaque envelopes (Allocation concealment). The envelopes will be opened in the order in which the participants enter the study.

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 Tabriz University of Medical Sciences

Street address

Azadi St., South Shariati, School of Nursing and Midwifery

City

Tabriz

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East Azarbaijan

Postal code

0415138947

Approval date

2021-02-22, 1399/12/04

Ethics committee reference number

IR.TBZMED.REC.1399.1078

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

Anxiety postpartum

ICD-10 code

F41

ICD-10 code description

Other anxiety disorders

2**Description of health condition studied**

distress in postpartum (after delivery)

ICD-10 code

O75.0

ICD-10 code description

Maternal distress during labor and delivery

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

Anxiety score

Timepoint

Before the intervention and 4 weeks after the intervention

Method of measurement

Spielberger Anxiety Questionnaire (Manifest Anxiety Scale)

2**Description**

Postpartum distress score

Timepoint

Before the intervention and 4 weeks after the intervention

Method of measurement
Postpartum Distress Questionnaire

3

Description

Breastfeeding self-efficacy score

Timepoint

Before the intervention and 4 weeks after the intervention

Method of measurement

Breastfeeding self-efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, during 6 sessions of 60 to 90 minutes of individual counseling, the stress management approach, which includes techniques such as relaxation, diaphragmatic breathing, meditation, recognizing negative automatic thoughts and reconstructing those thoughts by replacing logical thoughts, effective coping training and the skill of assertiveness, is applied.

Category

Behavior

2

Description

Control group: For the control group, a counseling session on contraceptive methods will be held for an average of 60-90 minutes.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mojahedin

Full name of responsible person

Shiva Shamsedanesh

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Name of recruitment center

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Name of recruitment center

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12**Recruitment center****Name of recruitment center**

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13**Recruitment center****Name of recruitment center**

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14**Recruitment center****Name of recruitment center**

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15**Recruitment center****Name of recruitment center**

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16**Recruitment center****Name of recruitment center**

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Shiva Shamsedanesh

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.Esmat Mehrabi

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Ph.Din Reproductive Health

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

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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

There is no more 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