Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
Age
From **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
Province
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
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Qom Tape

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Eram Health Center

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Sponsors / Funding sources

1

Sponsor
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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
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Shiva Shamsedanesh
Position
Master student of counseling in midwifery
Latest degree
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Person responsible for updating data

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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