

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Evaluating of the effectiveness of midwifery counseling based on Logo-therapy on anxiety and breastfeeding self-efficacy after breastfeeding Trauma

Protocol summary

Study aim

The effectiveness of midwifery counseling based on Logo-therapy on anxiety and breastfeeding self-efficacy after breastfeeding Trauma

Design

Clinical trial with 80 sample people and randomly assigning people to control and intervention groups

Settings and conduct

Eslamshar Emamreza Hospital

Participants/Inclusion and exclusion criteria

inclusion criteria: first birth, has not experienced an incident such as the death of a loved one, betrayal, divorce in the last month, confirmation of breastfeeding trauma according to the checklist, a person with a history of breast surgery that causes tissue damage ,the person has a desire to breastfeed,the score obtained from the Spielberger overt anxiety questionnaire should be 20-60,the baby should be healthy (no abnormality - not hospitalized,The person does not currently have a psychiatric disorder or a history of a psychiatric disorder for which she has visited a psychiatrist or taken medication, At least 4-6 weeks and at most three months have passed since childbirth. Exclusion criteria:mental disorder or having a history of mental disorder for which he has been referred to a psychiatrist and confirmed by him, consumption or history of taking psychiatric drugs,a score obtained from Spielberger overt anxiety questionnaire between 61 and be 80

Intervention groups

The intervention group: 40 women whose breastfeeding trauma has been confirmed according to the checklist and whose Spielberger manifest anxiety score is between 20 and 60. The people in the intervention group have 4 sessions of 60-minute meaning therapy counseling in groups of 8.they will receive routine postpartum care. The control group :40 women who have been confirmed to have breastfeeding trauma according

to the checklist. And their Spielberger anxiety score is between 20 and 60.

Main outcome variables

Anxiety and Breastfeeding Self-Efficacy after Breastfeeding Trauma

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231202060241N1**

Registration date: **2023-12-16, 1402/09/25**

Registration timing: **prospective**

Last update: **2023-12-16, 1402/09/25**

Update count: **0**

Registration date

2023-12-16, 1402/09/25

Registrant information

Name

Maryam Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2249 3576

Email address

rahimi.maryam13@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating of the effectiveness of midwifery counseling based on Logo-therapy on anxiety and breastfeeding self-efficacy after breastfeeding Trauma

Public title

Effectiveness of Logo-Therapy on Anxiety and Breastfeeding Self-efficacy after Traumatic Breastfeeding

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

First Child In the last month, Their has not experienced an incident such as the death of loved ones, betrayal, or divorce Confirmation of traumatic breastfeeding according to the checklist They have not a history of surgery on the breast that caused tissue damage and inability to breastfeed. Tend to breastfeeding Exclusive Breastfeeding The score obtained from Spielberger overt anxiety questionnaire should be 20-60 The Newborn should be healthy (no abnormality - not hospitalized) At least 4-6 weeks and at most three months have passed since Delivery They currently Dont have a psychiatric disorder or a history of a psychiatric disorder or take medication.

Exclusion criteria:

Mental disorder or having a history of mental disorder . Use or history of taking psychiatric medication The score obtained from the Spielberger overt anxiety questionnaire be between 61 and 80

AgeFrom **10 years** old to **54 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **80****Randomization (investigator's opinion)**

Not randomized

Randomization description**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 Shahroud University of Medical Sciences

Street address

No 13, Kowsar tower , Artesh High way, Tehran city

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Tehran

Province

Tehran

Postal code

1955856915

Approval date

2023-11-28, 1402/09/07

Ethics committee reference number

IR.SHMU.REC.1402.139

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

Traumatic Breastfeeding

ICD-10 code

O99.3

ICD-10 code description

Mental disorders and diseases of the nervous system complicating pregnancy, childbirth and the puerperium

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

Anxiety after Traumatic Breastfeeding

Timepoint

Before Intervention, After Intervention, Two Month after end of Intervention

Method of measurement

Spielberger State-Trait Anxiety Inventory

Secondary outcomes**1****Description**

Breastfeeding Self-efficacy

Timepoint

Before Intervention, After Intervention, Two Month after end of Intervention

Method of measurement

Denis Breastfeeding Self- Efficacy scale

Intervention groups

1

Description

Intervention group: The intervention group includes 40 mothers who are breastfeeding and 4-6 weeks to three months have passed since their delivery and have experienced Traumatic Breastfeeding. The intervention is midwifery counseling based on Logo-therapy in 4 sessions and each session take 60 minutes in groups of 8 people, in order to Evaluation the effectiveness of the midwifery counseling based on Logo-therapy on the anxiety and breastfeeding self-efficacy in women who suffer from Traumatic Breastfeeding, once a week and during a month + routine postpartum care will be done for women who are in the intervention group.

Category

Treatment - Other

2

Description

Control group: The control group includes 40 mothers who are breastfeeding and 4-6 weeks to three months have passed since their delivery and have experienced Traumatic Breastfeeding, and they take only routine postpartum care.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

EmamReza Hospital

Full name of responsible person

Maryam Rahimi

Street address

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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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Web page address

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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

Shahroud University of Medical Sciences

Proportion provided by this source

1

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

Shahroud University of Medical Sciences

Full name of responsible person

Maryam Rahimi

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the data included Questionnaires used in theses

Description of intervention sessions

When the data will become available and for how long

The access period starts one year after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For use in research projects and theses

From where data/document is obtainable

Rahimi.maryam13@yahoo.com Maryam Rahimi

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

After sending the email to me, the requested documents will be sent within a week.

Comments