

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating The Effect of The Motivational Enhancement Therapy (MET) on The Attachment to The Infant, Breastfeeding Self-Efficacy and Desire for Cesarean Section in Mothers Following Traumatic Childbirth

Protocol summary

Study aim

Determining the effect of The Motivational Enhancement Therapy on attachment to the infant, breastfeeding self-efficacy and Desire for Cesarean Section in Mothers Following Traumatic Childbirth

Design

A clinical trial with an intervention and control group, a blind strain, block randomization with R software, on 78 mothers after traumatic childbirth.

Settings and conduct

The study was conducted on mothers hospitalized in the post-partum department at Afzali pur and Payambar Azam Hospitals in Kerman in two intervention and control groups with a size of 39 people. The intervention is conducted in four sessions, the first in-person session 72 hours after delivery and the subsequent online sessions, one week, two weeks and three weeks after delivery, and the mother is evaluated 2 weeks after the sessions are completed.

Participants/Inclusion and exclusion criteria

Mothers within 72 hours after natural traumatic birth The baby is a singleton and full term No history of mental illness based on prenatal medical records Not taking antidepressants No death of a first degree relative within the last 6 months Having no contraindications for breastfeeding Absence of abnormalities, stillbirths in this pregnancy Mothers of infants who were admitted to the neonatal intensive care unit Diagnosis of postpartum depression by a psychiatrist or psychologist

Intervention groups

Intervention group: they receive 4 motivational Enhancement Therapy counseling sessions after delivery, check 2 weeks later after all the sessions Control group: receives routine care and check-up 5 weeks after delivery

Main outcome variables

The effect of The Motivational Enhancement Therapy on

traumatic childbirth, attachment to the infant, breastfeeding self-efficacy, desire for cesarean section

General information

Reason for update

Acronym

Motivational Enhancement Therapy

IRCT registration information

IRCT registration number: **IRCT20230622058555N1**

Registration date: **2023-07-08, 1402/04/17**

Registration timing: **prospective**

Last update: **2023-07-08, 1402/04/17**

Update count: **0**

Registration date

2023-07-08, 1402/04/17

Registrant information

Name

zahra kheirandish

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3216 7080

Email address

zahrakheirandish1400@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating The Effect of The Motivational Enhancement Therapy (MET) on The Attachment to The Infant, Breastfeeding Self-Efficacy and Desire for Cesarean Section in Mothers Following Traumatic Childbirth

Public title

Investigating The Effect of The Motivational Enhancement Therapy (MET) on The Attachment to The Infant, Breastfeeding Self-Efficacy and Desire for Cesarean Section in Mothers Following Traumatic

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Mothers Following Traumatic Childbirth Ability to read and write Ability to participate in counseling sessions Having a mobile phone with the ability to connect to one of the Iranian media messages The baby is a singleton and full term Mothers within 72 hours after natural traumatic birth

Exclusion criteria:

No history of mental illness based on prenatal medical records Not taking antidepressants No death of a first degree relative within the last 6 months Having no contraindications for breastfeeding Absence of abnormalities, stillbirths in this pregnancy Mothers of infants who were admitted to the neonatal intensive care unit Diagnosis of postpartum depression by a psychiatrist or psychologist

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: 78

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method with R software will be used to assign the sample to two control and intervention groups. The intervention group with We show "A" and the control group with "B", using R software, the way to assign people to each of the groups is as follows. ABBAABABAABBBBAAAABABBBAAAABBABBABBAABABA BAABBABABABABABABAABBABABAABAABBBABA After extracting the data from the questionnaire, they will be analyzed using spss software version 21

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding will be done for the stage of sample allocation and data analysis, block randomization method with R software will be used to allocate the sample to two control and intervention groups, and for data analysis, the information of individuals without specifying their group will be available. Statistical consultant is placed for analysis.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kerman University of Medical Sciences

Street address

Razi Faculty, University of Medical Sciences campus, At the beginning of Haft Bagh Blvd

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2023-06-06, 1402/03/16

Ethics committee reference number

IR.KMU.REC.1402.067

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

Mothers following a traumatic birth

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

Breastfeeding Self-Efficacy

Timepoint

Measurement of Breastfeeding self-efficacy before the intervention and 2 weeks after the intervention

Method of measurement

Breastfeeding self-efficacy questionnaire (Breastfeeding Self-Efficacy Scale-Short Form)

2

Description

The Attachment to The Infant

Timepoint

Measurement of The Attachment to The Infant before the intervention and 2 weeks after the intervention

Method of measurement

(Mother-to-infant Bonding Scale) MIBS

3

Description

Desire for Cesarean Section

Timepoint

Measurement of Desire for Cesarean Section before the intervention and 2 weeks after the intervention

Method of measurement

The score obtained from asking a question related to the mother's willingness to cesarean section

Secondary outcomes

1

Description

Traumatic childbirth

Timepoint

Within 72 hours after delivery

Method of measurement

At least one answer is yes

Intervention groups

1

Description

Intervention group: In the intervention group after traumatic natural childbirth, four 30-minute sessions of The Motivational Enhancement Therapy are held within 72 hours after delivery, one week, two weeks and three weeks after delivery, the mothers are evaluated before the intervention and two weeks after the completion of the sessions.

Category

Treatment - Other

2

Description

Control group: receives routine care and is evaluated within 72 hours after delivery and 5 weeks after delivery.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzali pour Hospitals

Full name of responsible person

Dr. Ahmed Anjam Shua

Street address

Imam Pardiseh Afzalipur Highway, Kerman

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kerman

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2

Recruitment center

Name of recruitment center

Payambar Azam Hospitals

Full name of responsible person

Dr. Farzin Kenya

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Reza Malekpour Afshar

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intdep2@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Firoozeh Mirzaee

Position

Assistant Professor

Latest degree

Ph.D.

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

Firoozeh Mirzaee

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work

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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 further 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