

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The effect of counseling with cognitive-behavioral approach (CBT) on self esteem and body image of lactating mothers: A quasi-experimental study

Protocol summary

Study aim

Determining the effect of pregnancy counseling with a cognitive behavioral approach on self-esteem and body image in lactating mothers: A quasi-experimental study

Design

Quasi-experimental study, with parallel groups, randomized Sample size 35 people in each group

Settings and conduct

Health centers of populated and culturally diverse areas of Tabriz

Participants/Inclusion and exclusion criteria

1. Minimum level of secondary education 2. Pregnancy age 25-28 weeks 3. First and second pregnancy 4. Singelton 5. Lack of disease affecting pregnancy, according to one's self (cardiovascular disease, preeclampsia, diabetes, epilepsy, etc.) 6. Not taking medications that affect one's mental health problems (sertraline, venlafaxine, deloxin, nortriptyline, etc.) 7. People with a body image score below 241 based on the MBSRQ questionnaire 8. Individuals with a self-esteem score lower than 25 based on the Rosenberg questionnaire Exclusion criteria 1. Having a history of severe depression, according to the individual 2. Hemorrhage in the second half of pregnancy

Intervention groups

For the intervention group, Cognitive Behavioral Approach, Body Image Based Cache and Starchen Training, and Self Esteem Based on Practical Guide to Group Cognitive Therapy by Michael Frey for 8 sessions of 60 to 90 minutes weekly. The control group will receive routine pregnancy care.

Main outcome variables

self-esteem, body image

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110524006582N33**

Registration date: **2020-08-19, 1399/05/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-19, 1399/05/29**

Update count: **0**

Registration date

2020-08-19, 1399/05/29

Registrant information

Name

Mahin Kamalifard

Name of organization / entity

Tabriz University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

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Email address

kamalifardm@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling with cognitive-behavioral approach (CBT) on self esteem and body image of lactating mothers: A quasi-experimental study

Public title

The effect of counseling on body image and self-esteem

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

At least secondary education gestational age between 25 to 28 weeks First or second pregnancy singleton No disease affecting pregnancy, according to the individual like(Cardiovascular Diseases,Preeclampsia,Diabetes,Epilepsy...) Not taking drugs that affect psychological problems, according to the individual like:(Sertraline,Venlafaxine,Deluxin,Nortriptyline...) Individuals with a body image score lower than 241 based on a Multidimensional Body-Self Relation Questionnaire Individuals with a self-esteem score below 25 based on the Rosenberg questionnaire

Exclusion criteria:

Having a history of severe depression, according to one's self Bleeding in the second half of pregnancy

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be assigned to intervention and control groups using randomized stratified method based on number of pregnancies (Stratification based on first pregnancy and second pregnancy) and size of four and six blocks.

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 Research in Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences Research

Administration

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2020-01-07, 1398/10/17

Ethics committee reference number

IR.TBZMED.REC.1398.1099

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

self esteem and body image

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

Comparison of the mean score of self esteem among the study groups

Timepoint

Before intervention, immediately after intervention, 1 month after delivery

Method of measurement

Rosenberg Self-esteem Questionnaire

2**Description**

Comparison of the mean score of body image among the study groups

Timepoint

Before intervention, immediately after intervention, 1 month after delivery

Method of measurement

Multidimensional Body-Self Relation Questionnaire

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

Comparison of the mean score of exclusive breastfeeding among study groups

Timepoint

1 month after delivery

Method of measurement

Designed exclusively breastfeeding checklist

Intervention groups

1

Description

Intervention group: People who will receive counseling with cognitive behavioral approach

Category

Behavior

2

Description

Control group: People who only will receive routine care.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of Tabriz

Full name of responsible person

Nasrin Zamiri-Miandoab

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No. Nesferah av, Jahad square, Ghareaghage st

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

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Golgasht Street, Research Office, No 2 Central Building, Tabriz University of Medical Sciences,

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Grant name

20%Grant active researchers

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

Mahin kamalifard

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Publishing in journals

When the data will become available and for how long

index of journal

To whom data/document is available

all people

Under which criteria data/document could be used

without any provision

From where data/document is obtainable

web page of journal

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

it will be define after publishing

Comments