Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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

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Iran (Islamic Republic of)

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+98 414796770

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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 singelton 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Mahin kamalifard
Position
Faculty member
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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