

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Evaluation of the effectiveness of midwifery counseling with the approach of acceptance and commitment on the mental image of the body and breastfeeding self-efficacy in pregnant mothers

Protocol summary

Study aim

Determining the effectiveness of midwifery counseling with an acceptance and commitment approach on body image and breastfeeding self-efficacy

Design

The clinical trial is a parallel type with two arms, one is the intervention group and the other is the control group. It is performed on 90 pregnant women who are eligible for the study. Block method with a volume of 4 to 45 people in the control group and 45 people in the intervention group are allocated.

Settings and conduct

90 pregnant women with inclusion criteria were included in the study from 8 comprehensive health service centers in Jajarm city and its suburbs, and randomly, 45 people were in the control group and 45 people were in the intervention group. The intervention group will then receive 8 sessions of admission-based counseling. The control group will receive only routine care. At the end of the counseling sessions, one month and three months after delivery, the questionnaires are completed by both groups and then the data analysis is performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: First pregnancy, gestational age 28 to 32 weeks, decision to exclusive breastfeeding, obtaining a cut-off score in the questionnaire, no smoking, no pregnancy problems, no major psychiatric illness
Inclusion criteria: Not available to pregnant mothers

Intervention groups

The intervention group, at separate times, receives 8 sessions of counseling based on acceptance and commitment in such a way that the first 4 sessions twice a week and the second 4 sessions once a week receive 10 people in each session for 90 minutes. The control group only Will receive routine care.

Main outcome variables

The first initial consequence is the mental image of the

body. The second primary consequence is the self-efficacy of breastfeeding.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210123050116N1**

Registration date: **2021-03-04, 1399/12/14**

Registration timing: **prospective**

Last update: **2021-03-04, 1399/12/14**

Update count: **0**

Registration date

2021-03-04, 1399/12/14

Registrant information

Name

Maryam sadat Hosini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3250 6146

Email address

hosinisadat370@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-11-06, 1400/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of midwifery counseling with the approach of acceptance and commitment on the mental image of the body and breastfeeding self-efficacy in pregnant mothers

Public title
Evaluation of the effectiveness of acceptance and commitment counseling on body image and breastfeeding self-efficacy

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
First pregnancy Single pregnancy Gestational age 28 to 32 weeks Decided to exclusive breastfeeding Obtain a cut-off score on the Multidimensional Body-Self Relationships Questionnaire At least literacy Familiarity with cyberspace No addiction to cigarettes, drugs and alcohol No problems during pregnancy (including pre Eklamsya, placenta previa, diabetes, Dklman) The lack of major psychiatric disease Lack of breast abnormalities Lack of medical prohibition on breastfeeding for mother and baby Previous non-participation in courses similar to this course Having the consent to enter the study Resident of Jajarm city and its suburbs
Exclusion criteria:
Absence for more than two sessions Relocation and unavailability of pregnant mothers

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the allocation sequence generated from the website www.sealedenvelope.com and based on the 4-volume block method, participants are randomly assigned to two groups. Because people enter the study over time and because This method was used over time to assign a proportion to the groups by accident, and also by assigning one person to a group, it is not possible to guess which group the next person will belong to. After generating the allocation sequence, each sequence letter (A, B) corresponds to a group. Since the participants enter the study from different centers, the central concealment method is used. The allocation sequence is in the hands of someone outside the research team. For each eligible person, after registering and entering the study, the desired person will be contacted and thus entered in a central list and will

receive an identification code and assigned to the desired group.

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
Research Ethics Committee of Shahroud University of Medical Sciences
Street address
Shahroud, Haftam Tir Square, Shahroud University of Medical Sciences and Health Services
City
Shahrood
Province
Semnan
Postal code
36147-73947

Approval date
2021-02-07, 1399/11/19

Ethics committee reference number
IR.SHMU.REC.1399.165

Health conditions studied

1

Description of health condition studied
The effectiveness of midwifery counseling with acceptance and commitment approach on body image and breastfeeding self-efficacy

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The score of the mental image of the body in the multidimensional body-self relations questionnaire

Timepoint
At the beginning of the study (before the intervention) and immediately after the intervention, one month and three months after delivery

Method of measurement
Based on the standard body-self multidimensional relationship questionnaire, which has 68 Likert-scale

questions, each question is scored from 1 (completely dissatisfied) to 5 (completely satisfied), so the minimum total score of an individual 68 and the maximum total score of a person can be 340. The scoring of the questionnaire is such that people who have a more appropriate mental image of themselves get higher scores. The cut-off score in this questionnaire is 142.

2

Description

Breastfeeding self-efficacy score in the standard breastfeeding self-efficacy questionnaire

Timepoint

At the beginning of the study (before the intervention) and immediately after the intervention, one month and three months after delivery

Method of measurement

Based on the standard breastfeeding self-efficacy questionnaire, which has 33 options and is rated on a 5-point Likert scale from strongly agree (score 5) to strongly disagree (score 1). Scores range from 33 to 165, and higher scores indicate higher levels of breastfeeding self-efficacy. A score of 33 to 76 is considered low self-efficacy, a score of 77 to 120 is considered moderate self-efficacy and a score of 121 to 165 is considered high self-efficacy.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: At separate times, 8 sessions of counseling based on acceptance and commitment (in case of outbreak of Covid disease 19 virtually) so that the first 4 sessions twice a week and the second 4 sessions once a week, 10 sessions in each session for They receive 90 minutes at the training hall of the same comprehensive health service center. The content of the meetings is based on the protocol of acceptance and commitment based on the six processes (acceptance, failure, self as a context, living in the present, recognizing values and committed action). These meetings will be held professionally by the project manager.

Category

N/A

2

Description

Control group:Receives only routine care, and at the end (a placebo intervention) is formed as a training session for the control group to maintain ethical standards that does not interfere with the counseling intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health service centers of Jajarm city and its suburbs

Full name of responsible person

Maryam Sadat Hosseini

Street address

Imam Reza Boulevard, Jajarm Health Network

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Jajarm

Province

North Khorasan

Postal code

9431148348

Phone

+98 58 3227 6014

Email

hosinisadat370@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hassan Emamian

Street address

3rd Floor, Bahar Research Center, Bahar Hospital, In front of Children's Park, 22 Bahman Ave.

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Shahroud

Province

Semnan

Postal code

3615739121

Phone

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Fax

+98 23 3239 4852

Email

emamian@shmu.ac.ir

Web page address

<http://www.shmu.ac.ir>

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

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**

Shahroud University of Medical Sciences

Full name of responsible person

Maryam sadat Hosini

Position

Student superior council in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Side Passage Votary, Banke Mellat, Department
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Postal code

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahroud University of Medical Sciences

Full name of responsible person

Maryam sadat Hosini

Position

Student superior council in midwifery

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Fax**Email**

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after identifying the names of individuals.

When the data will become available and for how long

Access period starts four months after the results are registered

To whom data/document is available

Researchers and students of medical universities

Under which criteria data/document could be used

The use of documents in all scientific and research activities is allowed, and to send a request for access to data and documents must be a student or researcher in the country's medical universities.

From where data/document is obtainable

To receive data, send an email to this address:

hosinisadat370@gmail.com

What processes are involved for a request to access

data/document

The student or researcher will send an email with the full content of the reason for requesting and using the data

to the email mentioned, and it will be sent to them as soon as they see the email.

Comments