

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The effectiveness of mindfulness-based cognitive counseling on body image concern in pregnant women

Protocol summary

Study aim

Determining the effectiveness of cognitive-behavioral counseling on the mind on awareness of dissatisfaction with appearance, on the reason of mindfulness on poor individual performance, on the image of pregnant women

Design

Clinical trial with control group and intervention group and assignment of individuals to each treatment group will be performed by randomized block method using 4 blocks

Settings and conduct

The researcher will refer to the management of comprehensive health centers No.1 in the east, Abuzar and west of Ahvaz with the aim of collecting samples

Participants/Inclusion and exclusion criteria

Entry requirements: 1) Being married 2) Being primiparous 3) 26 weeks of pregnancy 4) Conscious consent to participate in the study 5) Result of dissatisfaction with appearance in the body image anxiety questionnaire (score above 48) No entry conditions: 1. Taking medicine or hospitalization due to mental illness during the past year 2. Having major stress (serious illness, spouse or children, death of a loved one, migration, accident, severe family disorders) during the last six months 3. Simultaneous participation in other psychotherapy sessions

Intervention groups

Counseling sessions for the intervention group will be conducted in the form of 8 sessions of cognitive counseling based on mindfulness by the counseling student in the midwife who has received the necessary certificate. Therapeutic sessions are held once a week for 8 weeks and for 45 minutes in the conference hall of the client's comprehensive health centers. Will be provided from available sources. Routine pregnancy trainings will be performed in the control group

Main outcome variables

1) Mindfulness-based cognitive-behavioral counseling is

effective on appearance dissatisfaction and on poor individual performance 2) Mindfulness-based cognitive-behavioral counseling is effective in worrying about body image in pregnant woman

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20211218053448N1**

Registration date: **2022-02-02, 1400/11/13**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-02, 1400/11/13**

Update count: **0**

Registration date

2022-02-02, 1400/11/13

Registrant information

Name

Mehnoosh Farahabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3662 7413

Email address

mehnoosh.farahabadi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of mindfulness-based cognitive counseling on body image concern in pregnant women

Public title
The effect of mindfulness-based cognitive counseling on body image anxiety in pregnant women

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Being married Being primiparous 26 weeks of pregnancy
 Conscious consent to participate in the study Result of dissatisfaction with appearance in the body image anxiety questionnaire (score above 48)
Exclusion criteria:
 1. Taking medication or hospitalization due to mental illness during the past year Having major stress (serious illness, spouse or children, death of a loved one, migration, accident, severe family disorders) during the last six months Participate in other psychotherapy sessions at the same time

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Assignment of individuals to each of the treatment groups will be done by random block method and using 4 blocks individually and with a table of random numbers.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

Street address

Medical Sciences Blvd, Ahwaz Jundishapur University of Medical Sciences, School of Nursing and Midwifery

City

Ahwaz

Province

Khouzestan

Postal code

15794-61357

Approval date

2021-12-11, 1400/09/20

Ethics committee reference number

IR.AJUMS.REC.1400.549

Health conditions studied

1

Description of health condition studied

Concerns about the body image of pregnant women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Body image concern score on the Littleton questionnaire

Timepoint

Assessing the body image anxiety score of pregnant women at the beginning of the study (before the intervention) and at the end of the intervention (immediately after the intervention)

Method of measurement

Littleton Body Image Concern Questionnaire(BICI)

Secondary outcomes

1

Description

The degree of dissatisfaction with appearance

Timepoint

At the beginning of the study (before the intervention) and immediately after the intervention

Method of measurement

Littleton Body Image Concern Questionnaire (BICI)

2

Description

Poor individual performance

Timepoint

At the beginning of the study (before the intervention) and immediately after the intervention

Method of measurement

Littleton Body Image Concern Questionnaire(BICI)

Intervention groups**1****Description**

Intervention group: The sessions will be conducted in the form of 8 sessions of mindfulness-based cognitive counseling by a counseling student in midwifery who has been trained in cognitive-behavioral counseling courses and has received the necessary certification. Therapeutic sessions are held once a week on a specific day of the week, for 8 weeks and for 45 minutes in the conference hall of the client's comprehensive health centers. Consultation sessions will be held in groups due to the coronavirus epidemic with a limited number of people (4 people). The content of cognitive-behavioral therapy in each session will be presented under the supervision of supervisors and counselors and using available resources.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Comprehensive health center number one in East Ahvaz

Full name of responsible person

Zahra Abbaspour

Street address

Ahvaz - Ayatollah Behbahani Highway - Shahid Rastegari St. - Opposite Haft Tir Park - East Ahvaz Health Center

City

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Email

abbaspor_z762@yahoo.com

Web page address

http://www.ajums.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Zahra Abaspor

Street address

Medicine Blvd, Jondishapur Ahwaz University

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Email

mehnoosh.farahabadi@gmail.com

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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Mehnoosh Farahabdi

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehnoosh Farahabadi

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mehnoosh Farahabadi

Position

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Latest degree

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Other areas of specialty/work

Midwifery

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Boulevard of Medical Sciences, School of Nursing and
Midwifery, Ahvaz Jundishapur University

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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 potential data can be shared after identifying
individuals

When the data will become available and for how long

Start the access period after printing the results

To whom data/document is available

The data will be made available to people who need to
read me

Under which criteria data/document could be used

Documents are allowed to be used with reference to the
exact same

From where data/document is obtainable

mehnoosh.farahabadi@gmail.com 09162341532

Mehnoosh Farahabadi

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

One working week

Comments

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