Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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.1in 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 of8sessions 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 8weeks and for 45minutes 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, Ahvaz 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
Ahwaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 916 234 1532
Email
abbaspoor_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 Abaspur
Street address
Medicine Blvd, Jondishapur Ahwaz University
City
Ahwaz
Province
Khouzestan
Postal code
15794-61357
Phone
+98 61 3311 4114
Email
mehnoosh.farahabadi@gmail.com
Web page address
http://www.ajums.com
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
Medicine Blvd,Jondishapur Ahwaz University
City
Ahwaz
Province
Khouzestan
Postal code
15794 - 61357
Phone
+98 61 3311 0000
Email
mehnoosh.farahabadi@gmail.com

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

Street address
بلوار علوم پزشکی،دانشکده پرستاری و مامایی،دانشگاه جندی شاپور اهواز

City
Ahwaz

Province
Khouzestan

Postal code
15794 - 61357

Phone
33110000- 061

Email
mehnoosh.farahabadi@gmail.com

Person responsible for updating data

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

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

City
Ahwaz

Province
Khouzestan

Postal code
15794 - 61357

Phone
00980033110000

Email
mehnoosh.farahabadi@gmail.com

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
-