Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of mindfulness counseling on depression, stress and anxiety of pregnant women with a history of primary infertility

Protocol summary

Study aim
Investigating the effect of mindfulness counseling on depression, anxiety, and stress in pregnant women with a history of primary infertility.

Design
Clinical trial with two intervention and control groups, without blinding, simple randomized, intervention was conducted over 8 sessions on 88 people in the intervention group.

Settings and conduct
After identifying pregnant women with a history of primary infertility, if they met the criteria for participation in the study, the purpose of the study was explained to them. If they were willing and signed a written informed consent, they were randomly assigned to two intervention and control groups without blinding. Both groups completed a pre-test, and then 8 mindfulness sessions were held for the intervention group over 8 weeks, and after the intervention, both groups completed a post-test.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Informed consent to participate in the study 2. Being literate 3. Age between 20-40 years 4. History of primary infertility 5. Gestational age 14-20 weeks according to LMP or first trimester ultrasound 6. Mild to moderate stress, anxiety, and depression according to the DASS-21 questionnaire. 7. Pregnancy was achieved through assisted reproductive techniques. Exclusion criteria: 1. Fetal abnormality 2. History of mental illness according to the individual's report 3. Chronic physical illness 4. Experience of adverse events in the past three months 5- Previous receipt of psychological counseling services outside of treatment sessions

Intervention groups
For the intervention group, 8 sessions of mindfulness therapy on depression, anxiety, and stress of pregnant women with a history of primary infertility will be held. For the control group, routine care at Ahvaz health centers will be provided along with educational pamphlets.

Main outcome variables
depression, anxiety, and stress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241126063869N1**
Registration date: **2024-12-06, 1403/09/16**
Registration timing: **prospective**

Last update: **2024-12-06, 1403/09/16**
Update count: **0**

Registration date
2024-12-06, 1403/09/16

Registrant information

Name
Khadijeh Golnazari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-21, 1403/10/01

Expected recruitment end date
2025-04-21, 1404/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of mindfulness counseling on depression, stress and anxiety of pregnant women with a history of primary infertility

Public title
Investigating the effect of mindfulness counseling on depression, stress and anxiety of pregnant women with a history of primary infertility
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent to participate in the study Being literate Age between 20-40 years History of primary infertility Gestational age 14-20 weeks according to LMP or first trimester ultrasound Mild to moderate stress, anxiety, and depression according to the DASS-21 questionnaire. Pregnancy was achieved through assisted reproductive techniques.
Exclusion criteria:
Fetal abnormality History of mental illness according to the individual's report Chronic physical illness Experience of adverse events in the past three months Previous receipt of psychological counseling services outside of treatment sessions
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible individuals will be selected for the study using convenience sampling, and then participants will be divided into two intervention and control groups using simple randomization. The randomization method used in this study is the use of a random number table. A random number table is a set of numbers that are generated completely randomly without a specific pattern or order and are arranged in the form of a table. Initially, the direction of reading the numbers from the table was determined. The direction of reading the numbers from the random number table in this study is from the left, then even numbers extracted from the table were assigned to the intervention group and odd numbers extracted from the table were assigned to the control group. Each group consists of 44 participants. In this study, due to the nature of the interventions, blinding for the participants and the researcher is practically not possible due to the knowledge of the participants about being in the intervention group and the content of the sessions by the researcher, but the concealment of random allocation will be done centrally and by another person. This ensures that there is no bias in the selection of intervention and control groups and that the effects of the intervention are accurately and fairly assessed.
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 Jundi Shapur Ahvaz University of Medical Sciences
Street address
Esfand Ave.,Golestan Blvd,Ahvaz JundiShapour University of Medical Sciences
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2024-11-30, 1403/09/10
Ethics committee reference number
IR.AJUMS.REC.1403.476

Health conditions studied

1

Description of health condition studied
Stress, anxiety, depression
ICD-10 code
F41.2
ICD-10 code description
Mixed anxiety and depressive disorder

Primary outcomes

1

Description
Anxiety score in dass 21
Timepoint
Before the start of the intervention, immediately after the end of the intervention sessions, 4 weeks after the

end of the intervention

Method of measurement

Dass 21 questionnaire

2

Description

Depression score on dass 21

Timepoint

Before the start of the intervention, immediately after the end of the intervention sessions, 4 weeks after the end of the intervention

Method of measurement

Dass 21 questionnaire

3

Description

Stress score in dass 21

Timepoint

Before the start of the intervention, immediately after the end of the intervention sessions, 4 weeks after the end of the intervention

Method of measurement

Dass 21 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, 8 mindfulness counseling sessions will be held over 8 sessions of 1.5 to 2 hours. In order to evaluate the results of treatment, the relevant questionnaires will be completed by the participants before the start of the intervention, immediately after the end of the intervention, and 4 weeks after the end of the intervention and will be used for statistical analysis.

Category

Treatment - Other

2

Description

Control group: will receive usual care along with educational booklet. In order to evaluate the treatment results, the relevant questionnaires will be completed by the participants before the start of the intervention, immediately after the end of the intervention, and 4 weeks after the end of the intervention and will be used for statistical analysis.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

East Ahvaz Health Center

Full name of responsible person

Khadijeh Golnazari

Street address

Ayatollah Behbahani highway, in front of Haft Tir Park

City

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2

Recruitment center

Name of recruitment center

West Ahvaz Health Centers

Full name of responsible person

Khadijeh Golnazari

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Phone

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mehrnoosh Zakirkish

Street address

Golestan Aven.,, Research and Technology Vice-Chancellor of Jundishapur University of Medical Sciences and Healthcare Services, Ahvaz

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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
Zahra Abbaspour
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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Ahvaz University of Medical Sciences
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Khadijeh Golnazari
Position
Master student of midwifery counselling
Latest degree
Bachelor
Other areas of specialty/work
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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
The data of the study are classified and coded so that the names of the people cannot be identified.
When the data will become available and for how long
Access to the study data is possible after the results are published in the journal.
To whom data/document is available
All people who want to use the data in this field can access the study data.

Under which criteria data/document could be used

Study data can be used for comparison with other results.

From where data/document is obtainable

Dr.Zahra Abbaspoor Abbaspoor_z762@yahoo.com

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

The request is sent by e-mail to the person in charge of the scientific or general responsibility of the studyAbbaspoor_z762@yahoo.com

Comments