Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of mindfulness-based counseling on pregnancy anxiety in pregnant women with a history of stillbirth

Protocol summary

Study aim
Determining the effect of mindfulness-based counseling on pregnancy anxiety of pregnant women with a history of stillbirth

Design
The clinical trial has a randomized control group, an intervention and a control group of 50 people each, the type of randomization was block randomization with the size of 4.

Settings and conduct
The place of the study is the West and East health centers of Ahvaz city. The sample of the research is pregnant women referring to the health center who meet the conditions to entering the study. The participants are randomly assigned to two control and intervention groups. In the control group, there is no intervention, and in the intervention group, the counseling based on mindfulness is used. The treatment program will be provided by the researcher in the form of an 8-session program(two sessions per week). Meetings will be held in groups. Contents and assignments will be presented to the intervention group on a weekly basis. The way to follow up the samples in 4 stages is to fill the questionnaire in the first session (pre-test), the last session (post-test) one month and two months after the last training session.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Pregnant women with a gestational age of 14-24 weeks, a history of stillbirth in a previous pregnancy, having pregnancy anxiety (score 62 and above from the Vandenberg questionnaire) Exclusion criteria: unwanted pregnancy, occurrence of any mental disorder requiring medication during the intervention, termination of pregnancy before the end of the intervention

Intervention groups
Participants are randomly assigned to two control and intervention groups. There is no intervention in the control group and counseling based on mindfulness is used in the intervention group.

Main outcome variables
Pregnancy anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230716058808N1**
Registration date: **2023-07-21, 1402/04/30**
Registration timing: **prospective**

Last update: **2023-07-21, 1402/04/30**
Update count: **0**

Registration date
2023-07-21, 1402/04/30

Registrant information

Name
Maryam Bagherpour

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-06, 1402/05/15

Expected recruitment end date
2024-02-04, 1402/11/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mindfulness-based counseling on pregnancy anxiety in pregnant women with a history of stillbirth

Public title

The effect of mindfulness-based counseling on pregnancy anxiety

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women with a gestational age of 14-24 weeks History of stillbirth in previous pregnancy Singleton pregnancy Proficiency in Persian language Having Iranian nationality Having the ability to read and write Having pregnancy anxiety (score 62 and above from the Vandenberg questionnaire)

Exclusion criteria:

Unwanted pregnancy Occurrence of any mental disorder requiring medication during the intervention Termination of pregnancy before the end of the intervention Use of drugs or psychotropic substances Having medical and midwifery problems based on the medical record

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

For random allocation, considering that we have two intervention and control groups, we will use a block of 4. In order to determine the allocation sequence using the 4 block method, random allocation sequence generation software will be used. In order to hide the sequence of allocation, the papers identifying the group of people are placed inside the envelopes in the opaque package and coded in the same order.

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 Ahvaz Jundishapur University of Medical Sciences

Street address

Deputy of research and technology, Esfand Ave., Golestan Blvd., Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2023-07-08, 1402/04/17

Ethics committee reference number

IR.AJUMS.REC.1402.222

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Pregnancy anxiety

Timepoint

Before the intervention, immediately after the intervention, one month after the intervention, two months after the intervention

Method of measurement

Vanderberg Pregnancy Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Pregnant women with a history of stillbirth receiving mindfulness-based counseling. Mindfulness-based counseling uses mindfulness meditation practices and psychological strategies.In this method, mindfulness is based on 4 principles including Body awareness (body position and body movement/activity), body sensations (including

those related to emotions), mental states (including emotional states) and mental content (thoughts, images) are taught. In this study, the participants who meet the study entry criteria are randomly assigned to two control and intervention groups. In the control group, there is no intervention, and in the intervention group, the mindfulness-based counseling is used. Before starting the treatment program, the training certificate of the mindfulness course will be received and attached to the study, then the mindfulness-based counseling program for pregnancy anxiety in the form of an 8-session program during 4 weeks by The researcher will be presented. Meetings will be held in groups. Contents and assignments will be presented to the people of the intervention group on a weekly basis. It will be considered that the participants, whenever they have a problem in doing the assignments, have more interaction with the researcher in person or virtually to ensure the correctness of the assignments. How to follow up the samples in 4 steps by filling out the questionnaire The first session (pre-test), the last session (post-test), one month and two months after the last session after the last training session.

Category
Treatment - Other

2

Description
Control group: Pregnant women with a history of stillbirth without receiving mindfulness-based counseling

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
East Ahvaz Health Center

Full name of responsible person
Amralah Mardani

Street address
in front of Haft Tir Park - Shahid Rostagari street - Ayatollah Behbahani highway

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Ahvaz

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+98 61 3373 8331

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info@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Sahand Jorfi

Street address
Deputy of research and technology, Esfand Ave., Golestan Blvd., Ahvaz, Iran

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jorfi-s@ajums.ac.ir

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
Nahid Javadifar

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Ahvaz University of Medical Sciences, Golestan Blvd.

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Person responsible for scientific inquiries

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Person responsible for updating data

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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 de-identifying individuals.

When the data will become available and for how long
It will be possible to access the research documents six months after the final statistical analysis.

To whom data/document is available
The data will be available only for the use of researchers of academic institutions

Under which criteria data/document could be used
In order to promote childbearing

From where data/document is obtainable
In order to receive the data, people can refer to the main executive of the project, Dr. Nahid Javadifar, a member of the academic staff of Jundishapur University of Medical Sciences, Ahvaz. Email: nahidjavadifar_341@yahoo.com

What processes are involved for a request to access data/document
After obtaining the necessary permits from the Jundishapur University of Medical Sciences and the Vicechancellor of Research and Technology of this university, the applicant can proceed to receive the documents.

Comments