

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 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)

Phone

+98 61 3390 9121

Email address

maryambaghrpoor1396@gmail.com

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

Khuzestan

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: 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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6135715794

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+98 61 3373 8331

Email

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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Phone

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Email

nahidjavadifar_341@yahoo.com

Person responsible for scientific 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

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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

Person responsible for updating data

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

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