

# 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

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

6135715794

##### Phone

+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

#### City

Ahvaz

#### Province

Khuzestan

#### Postal code

6135715794

#### Phone

+98 61 3373 8383

#### Email

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

##### Street address

Ahvaz University of Medical Sciences, Golestan Blvd.

##### City

Ahvaz

##### Province

Khuzestan

##### Postal code

6135715794

##### Phone

+98 61 3373 8331

##### 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**

Midwifery

**Street address**

Ahvaz University of Medical Sciences, Golestan Blvd.

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135715794

**Phone**

+98 61 3373 8331

**Email**

nahidjavadifar\_341@yahoo.com

6135715794

**Phone**

+98 61 3373 8331

**Email**

nahidjavadifar\_341@yahoo.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 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**

Midwifery

**Street address**

Ahvaz University of Medical Sciences, Golestan Blvd.

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**