

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Effects of a mindfulness-based childbirth and parenting program on sleep quality of pregnant mothers with sleep disorders

#### Protocol summary

##### Study aim

Determining the effect of mindfulness-based delivery and parenting program on sleep quality of pregnant mothers with sleep disorders

##### Design

The interventional study is a pre-test-post-test in control and intervention Fifty-six pregnant women were divided into four groups of 23 controls and 23 intervention groups In order to hide the allocation, the numbers of the intervention and control groups are given to the group manager in blocks, respectively. People choose without seeing the numbers and are placed in groups of 8 people.

##### Settings and conduct

The study will be performed on 56 pregnant women with sleep disorders in East Ahvaz clinic as a clinical trial with two control and intervention groups. Who meet the inclusion criteria will be completed. and after obtaining written consent, the Pittsburgh Demographic Information Questionnaire and Sleep Quality Questionnaire will be completed by individuals who meet the inclusion criteria.

##### Participants/Inclusion and exclusion criteria

Being single Age 18 to 35 years Uncomplicated pregnancy (blood pressure, diabetes and other diseases) Lack of infertility Lack of chronic and underlying disease No depression and mental illness No addiction and no severe mental accident during the last 6 months absence from classes Participate in meditation and mindfulness classes at the same time Addiction

##### Intervention groups

Meetings are held once a week on a specific day and time in the counseling room, in groups for 1.5 hours. And after the sessions, the post-test is held in both groups. Counseling and training in this research will be done in groups by the researcher (Master of Counseling in Midwifery) who has participated in a mindfulness training course and obtained the necessary certificate.

##### Main outcome variables

Improving the sleep quality of pregnant mothers

Reduction and boredom during the day Reduce the risk of insomnia or lack of sleep

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220421054602N1**

Registration date: **2022-05-02, 1401/02/12**

Registration timing: **prospective**

Last update: **2022-05-02, 1401/02/12**

Update count: **0**

##### Registration date

2022-05-02, 1401/02/12

##### Registrant information

##### Name

Aysouda Azimi Igdir

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3654 1457

##### Email address

aysou.igdir@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-05-15, 1401/02/25

##### Expected recruitment end date

2022-06-05, 1401/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Effects of a mindfulness-based childbirth and parenting program on sleep quality of pregnant mothers with sleep disorders

**Public title**

Effects of a mindfulness-based childbirth and parenting program on sleep quality of pregnant mothers with sleep disorders

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Being single Age 18 to 35 Uncomplicated pregnancy (blood pressure, diabetes and other diseases) Lack of infertility Lack of chronic and underlying disease No depression and mental illness No addiction and no severe mental accident during the last 6 months

**Exclusion criteria:**

Participate in meditation and mindfulness classes at the same time

**Age**

From **18 years** old to **35 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **56**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The method of assigning the intervention to individuals is randomly divided into 4 groups of random permutation blocks with a random block size of 4 using the table related to random permutations and intervention and control. Randomization list prepared by a statistician To hide the allocation of individuals in the two intervention and control groups, 23 four-digit pairs will be selected as the codes of the participants in the control group and 23 4-digit individuals as the codes of the participants in the intervention group will be selected from a random number table. The numbers of intervention and control groups are written, then the blocks are placed in sealed envelopes, respectively, and are randomly delivered by one of the personnel to the qualified people to participate in the study. The researcher and the participant until the last moment They will not be aware of the type of allocation.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of ahvaz University of Medical Sciences

**Street address**

Ahvaz Golestan Highway, Jundi Shahpour University of Ahvaz

**City**

ahvaz

**Province**

Khouzestan

**Postal code**

15794 - 61357

**Approval date**

2022-04-09, 1401/01/20

**Ethics committee reference number**

IR.AJUMS.REC.1401.022

**Health conditions studied****1****Description of health condition studied**

sleep disorder

**ICD-10 code**

G47.9

**ICD-10 code description**

Sleep disorder, unspecified

**Primary outcomes****1****Description**

sleep disorder

**Timepoint**

At the beginning of the study and after the intervention

**Method of measurement**

Demographic Information Questionnaire and Pittsburgh Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Control group: No intervention is performed, only routine pregnancy care

**Category**

Treatment - Other

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### Description

Intervention group: Mindfulness counseling sessions are held once a week on a specific day and time in the counseling room, in groups and for 1.5 hours. After the sessions, post-test is held in both groups. However, in the control group, no training and counseling is given. The mindfulness-based cognitive therapy counseling model is adapted from the stress reduction model based on the Kabat-Zayn mindfulness method and the method based on childbirth and parenting that the principles of treatment Cognitive is added to it. In this study, the cognitive content of the sessions will be presented in a simple language and appropriate to the participants' level of understanding about the causes of sleep problems and symptoms and symptoms of insomnia, as well as treatment and reduction of sleep problems in pregnant women and childbirth and parenting.

### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

East Ahvaz Health Center

##### Full name of responsible person

Amraleh Mardani

##### Street address

East Ahvaz Health Center, Opposite Haft Tir  
ParkAyatollah Behbahani Highway - Shahid Rastegari  
St.

##### City

Ahvaz

##### Province

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+98 61 3311 5633

##### Email

info@ajums.ac.ir

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Mehrnoosh Zakir Kish

##### Street address

Ahvaz, University City, Vice Chancellor For Research  
And Technology, Ahvaz Jundishapur University Of  
Medical Sciences And Health Services, Ground Floor

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

6135715794

##### Phone

+98 61 3373 8383

##### Fax

##### Email

zakerkish-m@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

Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Midwifery

##### Street address

Jundi Shahpour University Of Ahvaz, Golestan  
Highway

##### City

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##### Province

Khouzestan

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15794 - 61357

##### Phone

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Nahid Javadifar

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Ahvaz Jundishapur University Of Medical Sciences

**Full name of responsible person**

Aysouda Azimi Igdir

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Hengam Alley No. 6/2, Niayesh St., Shiraz

**City**

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**Province**

Fars

**Postal code**

71948555543

**Phone**

+98 713 36541457

**Email**

Aysou.Igdir@Gmail.Com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available