Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

2

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
Khouzestan

Postal code
15794-61357

Phone
+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
Ahvaz

Province
Khouzestan

Postal code
15794 - 61357

Phone
+98 916 612 1693

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
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
Ahvaz Golestan Highway, Jundi Shahpour University Of Ahvaz

City
Ahvaz

Province
Khouzestan

Postal code
15794 - 61357

Phone
+98 916 612 1693

Email
Nahidjavadifar_341@Yahoo.Com

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
Shiraz

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