Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of mindfulness- based counseling and acupressure on pregnant women's sleep quality

Protocol summary

Study aim
The effect of mindfulness-based counseling and acupressure on sleep quality in pregnant women

Design
Two intervention groups and one control group, sample size of 90 people, we use the block permutation randomization method to randomly place the participants in three groups of 30 people.

Settings and conduct
the health centers and bases covered by the health center of Kashan city

Participants/Inclusion and exclusion criteria
Entry criteria: Iranian, normal pregnancy, Age 18-35 years, gestational age between 16-24 weeks, reading and writing literacy, willingness to participate in the study, Having an unfavorable sleep quality (getting a score of 5 or more later from completing the questionnaire) Nonentry criteria: not a smoker or drug abuse, and antidepressants and anxiety medications, Having Medical or psychological disease, Abnormal findings in the hands

Intervention groups
The intervention of the first group is counseling based on mindfulness, which includes attending 8 weekly 90-minute training sessions. The intervention of the second group consists of applying pressure with the thumb on the HT7 point (Shenman point) on the pea-shaped bone located in the wrists, for 5 minutes (10 seconds of pressure and 2 seconds of rest) once a night, before going to sleep, for 4 weeks. . The third group (control group) will only receive routine care and training according to the gestational age.

Main outcome variables
Sleep qualihy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230629058620N1**
Registration date: **2023-07-09, 1402/04/18**
Registration timing: **prospective**

Last update: **2023-07-09, 1402/04/18**
Update count: **0**

Registration date
2023-07-09, 1402/04/18

Registrant information

Name
Azam Toranjinejad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 5545 5220

Email address
a.toranjinejad@arakmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2024-01-10, 1402/10/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of mindfulness- based counseling and acupressure on pregnant women's sleep quality

Public title
Comparison of the effect of mindfulness- based counseling and acupressure on pregnant women's sleep quality
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Women with low-risk pregnancies Age 18-35 years Gestational age 16-24 weeks Literacy for reading and writing Willingness to participate in the study Having an unfavorable sleep quality (getting a score of 5 or more after completing the questionnaire)
Exclusion criteria:
Smoker or drug abuse Taking anti-depressants and anxiety medications Medical or psychological illness (such as diabetes, chronic hypertension, mental disease, etc.) abnormal findings in the hands
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: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
To randomize participants into three groups of 30 people (two intervention groups and one control group), we use the block permutation randomization method in order to balance the number of samples allocated in each group, and blocks of 6, with We arrange three letters ABC with equal letters as follows: block 1: BCACAB and BBCACA block 2: and block 3: BCAABC ..... and so on for different sequences. We select these blocks from the above permutations using random allocation software, which is capable of generating a random sequence by block method, and finally divide them into three groups: A (mindfulness intervention), B (acupressure intervention) and C. (control group) are divided.
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 Arak University of Medical Sciences
Street address
Basij Square (Sardasht), Arak University of Medical Sciences, University Complex of the Great Prophet (PBUH), Deputy for Research and Technology
City
Arak
Province
Markazi
Postal code
3848176341
Approval date
2023-06-06, 1402/03/16
Ethics committee reference number
IR.ARAKMU.REC.1402.069

Health conditions studied

1

Description of health condition studied
Sleep quality in pregnancy
ICD-10 code
G47.8
ICD-10 code description
Other sleep disorders

Primary outcomes

1

Description
Sleep quality score
Timepoint
Before the interventions, immediately and one month after the interventions
Method of measurement
Pittsburgh Standardized Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention of the first group of counseling on mindfulness: which includes 8 weekly 90-minute training sessions in groups (groups of 15 people) that will be delivered to the supervisors and counselors. The researcher will train the mind with the help of teaching and response techniques, role playing, doing class and homework assignments. The sessions will be based on basic training and exercises such as meditation, body scan, mindfulness meditation, and three-minute breathing exercises, etc., which will focus on paying attention to the events taking place in the present and understanding and accepting these events

without any judgment and It will teach judgment to pregnant mothers and finally mothers will learn that instead of denying or avoiding negative thoughts and unpleasant events, they accept them and are aware of their reaction to them and show an appropriate reaction in dealing with them. give In the first session, a homework sheet will be provided to mothers, which they must complete weekly. The sessions will be held in the training hall of Kashan health centers, and the researcher who has already completed the specialized counseling course based on mindfulness and will conduct the sessions under the supervision of the clinical psychologist who is a member of the research. In order to evaluate the effectiveness of mindfulness counseling, the participants will be asked to complete the Pittsburgh Sleep Quality Questionnaire after the eighth session and also 1 month after the completion of the mindfulness training sessions.

Category

Other

2

Description

The second group is the acupressure intervention, which is performed in the form of individual and face-to-face acupressure training on the HT7 point (Shen Man point) on the pea-shaped bone of the wrists (in the transverse crease of the wrists in the angle between the pea-shaped bone and the ulnar bone). It will include the pressure applied by the thumb on the mentioned point for 5 minutes (10 seconds of pressure and 2 seconds of rest). After 5 minutes, the same thing is done on the desired point on the other hand. In total, each intervention takes 10 minutes. The pressure is applied for 5 minutes in such a way that the pregnant mother feels warmth, heaviness, swelling or numbness at that point. The process of intervention is 1 time at night, before sleep and for 4 weeks. Before starting the research, the researcher should be trained in acupressure and acquire the necessary skills to find the desired point with 100% accuracy and correctly identify the desired point on 10 participants. The training of the participants in the study regarding the method of finding the desired point and the amount of applying pressure on it will be done verbally and in writing by presenting a pamphlet by the researcher. The participants will be invited to perform acupressure on the mentioned points once in the presence of the researcher so that necessary guidance can be provided if needed. Then the participants in the intervention will complete the Pittsburgh Sleep Quality Questionnaire immediately after the 4-week intervention and 1 month after the end of the intervention. The intervention of this group will be done one month after the intervention of the first group so that the time to complete the Pittsburgh sleep quality questionnaire is the same in all three groups.

Category

Other

3

Description

Control group: receiving routine care and training according to the gestational age and completing the Pittsburgh sleep quality questionnaire at the time of entering the study, 8 weeks later and 12 weeks later.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Development Center of Network Management and Health Promotion of Kashan Health Center

Full name of responsible person

Azam Toranjinejad

Street address

No.17,Tovhid 18 Alley, 22 Bahman Street

City

Kashan

Province

Isfehan

Postal code

8715178145

Phone

+98 31 5545 5220

Email

a.toranjinejad@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Davood Hekmatpou

Street address

Basij Square (Sardasht), Arak University of Medical Sciences, University Complex of the Prophet (PBUH), Research and Technology Vice-Chancellor

City

Arak

Province

Markazi

Postal code

3848176341

Phone

+98 86 3417 3532

Fax

Email

dr_hekmat@arakmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Azam Toranjinejad

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No.17,Tovhid 18 Alley , 22 Bahman Street

City

Kashan

Province

Isfehan

Postal code

8715178145

Phone

+98 31 5545 5220

Email

a.toranjinejad@arakmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Fereshteh Farzanazar

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Basij Square (Sardasht), Arak University of Medical Sciences, Faculty of Medicine

City

Arak

Province

Markazi

Postal code

3848176341

Phone

+98 86 3383 8237

Email

farzanazar@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Azam Toranjinejad

Position

Masters Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No.17, Tovhid 18 Alley , 22 Bahman Street

City

Kashan

Province

Isfehan

Postal code

8715178145

Phone

+98 31 5545 5220

Email

a.toranjinejad@arakmu.ac.ir

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

No - There is not 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

Publication in the article

When the data will become available and for how long

Six months after the end of the study

To whom data/document is available

Health care centers, managers, training centers

Under which criteria data/document could be used

Educational, therapeutic and planning use

From where data/document is obtainable

Public respondent

What processes are involved for a request to access data/document

First, it should be requested and approved by the Research Vice-Chancellor of Arak University of Medical Sciences. Then correspond with the public respondent

Comments