Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Investigating the effect of cognitive-behavioral counseling based on mindfulness on the sleep quality of primiparous mothers in the postpartum period

Protocol summary

Study aim
Determining the impact of cognitive-behavioral counseling based on mindfulness on the sleep quality of primiparous mothers in the postpartum period

Design
After selecting the samples, they will be divided into two groups using a random block of 6 and with an allocation ratio of 1.1. Each of the blocks will have 3 people from the control group and 3 people from the intervention group. It is random.

Settings and conduct
Samples are collected in 17 Shahrivar and Abu Dhar centers. The samples will be selected from among the mothers who are eligible and who meet the entry criteria and do not have the exit criteria. To hide the random allocation, the type of intervention will be written on paper and placed inside the opaque envelopes numbered consecutively. In this way, the researcher and the participant will not know the type of intervention until the start of the intervention. Due to the nature of this study, blinding will not be possible.

Participants/Inclusion and exclusion criteria
Entry conditions: primiparous mothers 6 months after giving birth - mothers with poor sleep - absence of any mental and physical illness - natural and uncomplicated birth - birth of a healthy and mature baby - singleton - exclusive breastfeeding - at least the end of primary school education - Age range - 1 to 40 years - proficient in Persian language Conditions of non-entry: postpartum depression - hospitalization of the baby for any reason - suffering from an acute febrile illness during research - suffering from chronic diseases such as diabetes

Intervention groups
This research is a type of clinical trial intervention that investigates the effect of cognitive-behavioral counseling based on mindfulness on the quality of sleep of mothers with first-born children in the postpartum period.

Main outcome variables
Sleep quality in the Pittsburgh Questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230718058833N1**
Registration date: **2023-08-29, 1402/06/07**
Registration timing: **prospective**

Last update: **2023-08-29, 1402/06/07**
Update count: **0**

Registration date
2023-08-29, 1402/06/07

Registrant information

Name
Simin Khezri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 77 3353 5404

Email address
khezri.s@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-03, 1402/06/12

Expected recruitment end date
2024-01-02, 1402/10/12

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of cognitive-behavioral counseling based on mindfulness on the sleep quality of primiparous mothers in the postpartum period

Public title

Investigating the effect of cognitive-behavioral counseling based on mindfulness on the sleep quality of mothers

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Primiparous mothers six months after delivery Absence of any mental or physical illness Natural birth without complications The birth of a healthy and mature baby monogamy Exclusive breastfeeding Minimum education at the end of elementary school Age range from 18 to 40 years Proficient in Persian language

Exclusion criteria:

Postpartum depression (getting a score above 5.12 from the Edinburgh Depression Questionnaire) Hospitalization of the baby for any reason Getting an acute febrile illness during research Having chronic diseases such as diabetes

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **98**

Randomization (investigator's opinion)

Randomized

Randomization description

After the initial selection of the samples, they will be divided into two groups using a random block of 6 and with an allocation ratio of 1.1. In each of the blocks, 3 people will be in the control group and 3 people will be in the intervention group. He is a random person.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

In order to hide the random allocation, the type of intervention will be written on paper and placed inside opaque envelopes numbered consecutively, in this way, the researcher and the participant will not know the type of intervention until the intervention begins. This study will not be able to blind the researcher and the participant.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz University of Medical Sciences

Street address

Golestan St., Jundishapur University of Medical Sciences, Ahvaz, Nursing and Midwifery College

City

Ahvaz

Province

Khouzestan

Postal code

6135715749

Approval date

2023-08-15, 1402/05/24

Ethics committee reference number

IR.AJUMS.REC.1402.289

Health conditions studied

1

Description of health condition studied

Sleep quality

ICD-10 code

G47

ICD-10 code description

Sleep disorders

Primary outcomes

1

Description

Sleep quality in the Pittsburgh Questionnaireا

Timepoint

At the beginning of the study, week 8 (immediately after the intervention), week 12 after the intervention (one month after the intervention)پ

Method of measurement

Pittsburgh Sleep Quality Questionnaire-Edinburgh Depression Scale

Secondary outcomes

1

Description

Sleep quality score

Timepoint

8 weeks (immediately after the intervention) and 12 weeks after the intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire-Edinburgh

Depression Scale

Intervention groups

1

Description
Intervention group: The intervention group will be divided into 4 groups, then the intervention will be carried out in the form of a pre-test, post-test and follow-up stage, so that all the mothers of the intervention and control groups at the beginning of the study, week 8 and week 12 after the intervention of the sleep quality questionnaire will be completed by self-reporting.The purpose of this study is to determine the effectiveness of cognitive-behavioral counseling based on mindfulness on the sleep quality of primiparous mothers in the postpartum period. and if they have entry criteria and no exit criteria, the samples will be selected, at first, each eligible person will be given the same explanation about the objectives of the research and how to intervene. Completing the demographic questionnaire, the Edinburgh Depression Scale and the sleep quality questionnaire by Samples that meet the conditions for entering the study will be conducted. Counseling will be conducted by a trained researcher under the supervision of a consultant professor at the center. The women of the intervention group will undergo 8 group counseling sessions (1 session per week) with a cognitive therapy approach based on Mindfulness will be aimed at improving the quality of sleep. Sessions will be held in groups, one 45-minute session per week for 2 months according to the plan between the consultant and the clients.

Category
Behavior

2

Description
Control group: Control group: This group consists of 49 people. In each of the blocks, 3 people will belong to the control group and 3 people will belong to the intervention group, and the order of placement of each person is random. Low sleepers will not receive any intervention, in order to comply with ethical standards, they will be given a training booklet and a summary of the contents of the sessions.

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Seventeen Shahrivar Health Center
Full name of responsible person
Dr. Naheed Javadi Far
Street address
Thirty meters, Rostagari Street, Gandami Street
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3373 8331
Email
nahidjavadifar_341@yahoo.com

2

Recruitment center
Name of recruitment center
Abu Dhar Health Center
Full name of responsible person
Dr. Naheed Javadi Far
Street address
Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6135715749
Phone
+98 61 3373 8331
Email
nahidjavadifar_341@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Mehrnoosh Zaker Kish
Street address
Ahvaz Academic City - Research and Technology Vice-Chancellor of Jundishapur University of Medical Sciences, Ahvaz - ground floor
City
Ahvaz
Province
Khouzestan
Postal code
6135715749
Phone
+98 61 3333 3477
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
Dr. Naheed Javadi Far

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
Khuzestan, Ahvaz, Golestan St., Jundishapur University of Medical Sciences, Ahvaz Faculty of Nursing and Midwifery

City
Ahvaz

Province
Khouzestan

Postal code
6135715749

Phone
+98 61 3373 8331

Email
Nahidjavadifar_341@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Dr. Naheed Javadi Far

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
Khuzestan-Ahvaz-Jandishapur University of Medical Sciences, Ahvaz Faculty of Nursing and Midwifery

City
Ahvaz

Province
Khouzestan

Postal code
6135715749

Phone
+98 61 3373 8331

Email
Nahidjavadifar_341@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Simin Khezri

Position
Master's student in counseling in midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Behesht Sadegh Square, Shahid Korehbandi Street, Plate 12

City
Bushehr

Province
Boushehr

Postal code
7514873456

Phone
+98 77 3353 5404

Email
khezri.s@ajums.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
Not applicable

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Only part of the demographic information of the patients and the main outcome can be shared.

When the data will become available and for how long
6 months after the results are published

To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
Mentioning the name of the study and mentioning the name of the researchers

From where data/document is obtainable

Simin Khezri, Faculty of Nursing and Midwifery, Jundishapur University of Medical Sciences, Ahvaz

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

A maximum of one month after the request

Comments