

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Evaluation of mindfulness group based counseling on sleep quality in nulliparous pregnant women

Protocol summary

Study aim

Determination of the effect of mindfulness based group counseling on the sleep quality of pregnant women

Design

Controlled randomized controlled trials, with a two-group research project (intervention and control), a post test & pretest, with a sample size for each group of 20 people.

Settings and conduct

By referring to the Golha health centers in Gorgan; and according to inclusion and exclusion criteria for this study, the subjects selected via accessible sampling. If they would like to participate in the study and Based on permuted block randomization via random sequence generation sampling method, will be randomly assigned to both control and intervention groups. Meanwhile, both groups will be included in the study the same times.

Participants/Inclusion and exclusion criteria

Entry requirements: Pregnancy women who are on the basis of the date of the last menstruation or ultrasound, at least 14 weeks of pregnancy and up to 24 weeks. Pregnant women with poor sleep quality Non-arrival conditions: use of sleep medications and housing Participate in similar training courses in pregnancy

Intervention groups

The intervention group: will be mind-boggling in groups of 6 to 12, in the course of 8 sessions per week, 120 minutes. Control group: Without receiving any intervention, after completing the first stage of the questionnaire, 8 and 12 weeks later, they will be examined for sleep quality.

Main outcome variables

quality of sleep during pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180408039229N1**

Registration date: **2018-08-03, 1397/05/12**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-03, 1397/05/12**

Update count: **0**

Registration date

2018-08-03, 1397/05/12

Registrant information

Name

Narjes Sadat Borghei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3254 9718

Email address

dr.borghei@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of mindfulness group based counseling on sleep quality in nulliparous pregnant women

Public title

Evaluation of mindfulness on sleep quality

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Nulliparous Pregnant women Gestational age between 14 to 24 weeks. Pregnant women with poor sleep quality that score 5 or more than 5 of the Pittsburgh Sleep Quality Index. Have read and write literacy. By the end of pregnancy, they should be residents of Gorgan. fluent in Farsi

Exclusion criteria:
Experience a severe stressful event during the past 3 months (eg accident, the death of one of the first-degree relatives) High-risk pregnancy based on the country's guidelines for the provision of obstetric and obstetric services The use of hypnotic and analgesic drugs Participate in similar training courses in pregnancy (such as attending special pregnancy classes) infertility History drug misuse, psychotropic or alcohol abuse woman having a known psychological illness and the use of psychiatric drugs or physical illnesses (cancers) and chronic diseases in the last few months shift in working hours and night work

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 40

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Restricted randomization with block randomization permuted Random unit: Individual permuted block randomization via random sequence generation. For this purpose scores is arranged in ascending order and placed between two and two to the control and test groups. also In the randomization process, the person involved in the creation of a random program will be distinct from other researchers, to reduce the probable bias.

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 Golestan University of Medical Sciences

Street address

Research Deputy of Golestan University of Medical Sciences, Beginning of the Road of Shasta Kalateh., 5th Km of Gorgan Kurdkuy Road

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2018-02-25, 1396/12/06

Ethics committee reference number

ir.goums.rec.1396.286

Health conditions studied

1

Description of health condition studied

poor sleep quality during pregnancy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

sleep quality during pregnancy

Timepoint

Before the intervention, the end of the intervention and one month after the intervention

Method of measurement

Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group will counsel in 6 to 12 people, 120 consecutive minutes will be subject to group counseling during the 8 weekly sessions. Session 1: Participants are asked to introduce themselves at the first meeting. The researcher will give them a brief summary of 8 sessions. Afterwards, participants will be asked eating a raisin number with all the emotions and discussing this feeling in the future. Body scan is then performed for 30 minutes. Second session: Participants will encourage their body scans to meditate, and discuss their experiences with their homework experience. After that, discussing the barriers to practicing and solving the mindfulness program is discussed. Then discusses the difference between thoughts and feelings and finally

meditate in a sitting position. Session 3: Begins with the practice of seeing and hearing. In this exercise, participants are asked to look in a non-judgmental fashion for 2 minutes and listen. At the fourth session, with attention to breathing, body sounds and thoughts begin. In the following, discuss stress responses and one's reaction to difficult situations and alternative behaviors, and at the end of the session, walking into the conscious mind is practiced. At the fifth session, participants are asked to take meditation sessions. In the second part of the second cycle, the conscious movements of the body are presented and implemented. The sixth session begins with a three-minute breathing exercise. After that, the practice is presented with this theme: the content of the thoughts are not mostly real. Seventh session begin With a four-dimensional and intelligible mediation, he will be alert to everything at the moment. The theme of this meeting is: What is the best way to self care? Session 8: After performing meditation, body scan and 3-minute breathing exercises; the methods of coping with barriers to mediation is discussed. Then, in the case of the whole session, questions about what do participants feel that their coping skills have increased and whether they want to continue their meditation exercises; it will be discussed.

Category

Behavior

2

Description

Control group: There is no intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Golha health centers

Full name of responsible person

Niazy, Somayeh

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Golha health center., No.1, Golbarg., Golha street., Gorgan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

honarvar, Mohammad Reza

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Narjes Sadat Borghei

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Position
Assistant professor
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Bachelor
Other areas of specialty/work
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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

After being unidentified, sharing information on the main outcome can be shared.

When the data will become available and for how long

There will be access 6 Month after publication

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

More advanced analyzes on the main outcome, provided the written consent of the researchers.

From where data/document is obtainable

Email

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

3 month after email to the Correspondence author

Comments