Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Mindfulness Interventions on the Quality of Sleep in Pregnant Mothers in the second and Third Trimester

Protocol summary

Study aim
The Effect of Mindfulness Interventions on the Quality of Sleep in Pregnant Mothers in the second and Third Trimester

Design
A sample of 32 pregnant women who go to Sabzevar Health Centers will be selected by available sampling method and will be randomly assigned to two experimental and control groups (16 people each). After completing the pre-test, the 8-session test group They will be trained in mindfulness exercises and the control group will be taught mindfulness exercises in one session in addition to the usual pregnancy care.

Settings and conduct
It is semi-experimental and pre-test-post-test with the control group. Among all pregnant women who will go to Sabzevar Health Center in 1398 to receive double pregnancy care. A sample of 32 people will be selected by available sampling method and will be randomly assigned to two experimental and control groups (16 each).

Participants/Inclusion and exclusion criteria
Interest in participating in educational programs, lack of chronic physical illnesses (diabetes, high blood pressure, kidney disease and asthma, etc.), lack of a history of psychiatry, prolonged pregnancy risk (miscarriage and bleeding)

Intervention groups
For 42 pregnant mothers, the effectiveness of mindfulness intervention will be on their sleep quality, and for the control group, one session will be scheduled at the end.

Main outcome variables
Improving the sleep of pregnant mothers - reducing depression and anxiety in these mothers

General information

Reason for update

Acronym
mfspm

IRCT registration information
IRCT registration number: **IRCT20191204045601N1**
Registration date: **2020-07-08, 1399/04/18**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-08, 1399/04/18**
Update count: **0**

Registration date
2020-07-08, 1399/04/18

Registrant information

Name
Raziye Shamabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-21, 1399/04/01

Expected recruitment end date
2020-08-22, 1399/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Mindfulness Interventions on the Quality of Sleep in Pregnant Mothers in the second and Third

Trimester

Public title
The Effect of Mindfulness Interventions on the Quality of Sleep in Pregnant Mothers in the second and Third Trimester
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Having the ability and interest to participate in educational programs, not attending similar training classes, lack of chronic physical illnesses (diabetes, hypertension, kidney and asthma, etc.), lack of psychiatric background, , minimum age of participant It will be 20 years and maximum 34 years. .minimum diploma education According to the Sleep Quality Questionnaire, a score above 5 according to the questionnaire indicates poor sleep quality
Exclusion criteria:
According to the participant and inability to continue,ed pregnancy to high-risk pregnancy (risk of miscarriage and bleeding), preterm labor (preterm delivery above 38 weeks), acute stress during the course, regular absence in training sessions, and failure to attend The exercises will be at home.
Age
From **20 years** old to **34 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, a sample of 84 pregnant women in the second and third trimesters who refer to Sabzevar health centers will be assigned to study and control groups using closed envelopes and individual lottery. The blocking method is randomly selected by replacing the envelope Type of randomization: Blocked randomization
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
Mashhad Medical Sciences Ethics Committee
Street address
Mashhad University of Medical Sciences
City
sabzavar
Province
Razavi Khorasan
Postal code
9177948564
Approval date
2019-08-13, 1398/05/22
Ethics committee reference number
ir.mums.medical.REC.1398.572

Health conditions studied

1

Description of health condition studied
Effectiveness of mindfulness on the quality of sleep of pregnant mothers
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sleep quality (pregnancy is an event that changes many aspects of a woman's life. It affects a woman's health and social roles and sometimes causes psychological problems in them. One of the problems during pregnancy is sleep disorders and a large percentage Pregnant women (especially in the third trimester of pregnancy) suffer from a change in the normal pattern of sleep and its disturbances, due to the fact that sleep disorders can cause many complications before, during and after childbirth.
Timepoint
two months
Method of measurement
Filling the Pittsburgh Sleep Quality Questionnaire (PSQI) and training during mindfulness sessions for mothers

2

Description
Depression includes mood swings, lack of self-confidence, hopelessness, lack of value in life, lack of interest in conflict, lack of enjoyment of life, and lack of energy and power.
Timepoint
two months
Method of measurement
Depression, Anxiety and Stress Questionnaire (DASS-21)

3

Description

Anxiety includes things like physiological hyperactivity, fears, and situational anxiety

Timepoint

two months

Method of measurement

Depression, Anxiety and Stress Questionnaire (DASS-21)

4

Description

two months

Timepoint

two months

Method of measurement

Depression, Anxiety and Stress Questionnaire (DASS-21)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study, a sample of 84 pregnant women in the second and third trimesters who refer to Sabzevar Health Centers was selected by available sampling method and randomly placed in two experimental and control groups (42 people each). . Upon completion of the pre-test, the 6-session intervention group will be trained in mindfulness exercises and will be given a questionnaire for sleep quality and dass21 questionnaires. And the interview will be conducted by a neuropsychiatrist. Individuals with a score above 5 in the sleep quality questionnaire have poor sleep quality (and, according to the 21dass questionnaire, their severity of moderate to severe depression are in the intervention group. The experimental group will be completed after the mindfulness interventions of the post-test questionnaires. First session: Automatic guidance (When we notice the automatic guidance, we find the presence of the mind) It can be busy; you go from job to job without having a chance to smell a beautiful flower. D or find out what's going on around you. In other words, it's your automatic guide that has control over you. A great way to regain control is to take time for meditation called "Mindfulness of Body and Soul." A simple eight-minute exercise designed to focus on the present. Second session: Focusing more on the body (focusing on the body reveals more mental whispers and leads to more control over the reaction to daily events). It is designed so that you can focus on your body. The body speaks very well. When he says he's hungry, it's almost impossible not to understand what he wants. However, they are a little more nuanced and easy to ignore, and the goal of a 14-minute "body scan" is to open the way for communication between your body and mind. It blows with every breath and with every exhale, it is empty. Pay attention to how you feel while doing this; For example, tingling in the legs or nausea. Remember that there is no winning or losing or failure. If he gets distracted, try to get him back to practice. Do this exercise twice a day for a week. Third session: By learning how the mind can often be busy and scattered, we learn to focus more consciously on breathing to provide more focus and integration. In the third session, it's time to take care of the "three-minute breath" that you have to do twice a day. At this point, take two minutes to focus on your emotions, thoughts, and body, then one minute for deep breathing, and focus on the inhale and exhale. Fourth session: Most often, when the mind wants to focus on something and avoid other things. It is wasted. In the mind-to-face approach to being present at the same time, one must look at events from a different angle in order to have a broad and different view of them. In this session, you should learn how to distance yourself from your thoughts. The meditation you are about to do is called "sounds and thoughts" or "sounds and thoughts": you do nothing for eighty minutes and you only pay attention to the sounds around you. When you realize that sounds come and go like tides, know that you've done the exercise right. When you are fully focused, your mind begins to tell a story based on the sounds you hear; For example, from a loud noise, it is thought that a cement brick has fallen from the roof. This meditation is a great way to learn how your mind works. At the end of the week, you will be much more comfortable with the flow and nature of your thoughts. Or try to change it for what it is. The exercise you do every day for ten minutes a week is called "Searching for Difficulties." Whenever you are ready, turn your thoughts to a difficult or unpleasant subject. Whatever it is; From your childhood illness to your child's poor grades in school. Try to figure out where you feel the thought in your body as soon as you find that point, while taking deep breaths, let those feelings be absorbed. This is the moment of acceptance and compassion that prepares you to be free and comfortable. Combine this meditation with previously learned meditations: "Body and Soul," "Sounds and Thoughts," "Searching for Difficulties," and "Three-Minute Breathing." Understanding that thoughts are just thoughts is reasonable, even for someone who doesn't believe it. This session is about a very general reason, which is another aspect of how to do it. A very general memory is a tendency to recall events from the past in a completely negative way. For example, you may feel awful throughout your high school years, when you really only have an unpleasant class. When you feel this way, you are easily blaming yourself and others. But blaming doesn't help reconcile with the past. In fact, research has shown that it makes it even more difficult.

Category

Lifestyle

2

Description

Control group: People will be given a sleep quality questionnaire and dass21. And the interview will be conducted by a neuropsychiatrist. People who do not have a problem with sleep quality according to the sleep

quality questionnaire (and do not suffer from depression according to the 21dass questionnaire) are in the control group and routine pregnancy care is done for the control group.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Sabzevar Health Center

Full name of responsible person

Razie Shamabadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Negar Asgharipoor

Position

University professor

Latest degree

Specialist

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Name of organization / entity

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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
No - There is not a plan to make this available