Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Mindfulness-based counseling on Pregnant women with anxiety disorders experience of Preterm birth

Protocol summary

Study aim
Determining the effect of mindfulness counseling on anxiety in pregnant women with a history of preterm delivery

Design
Clinical trial with control group, with parallel groups and the volume of each group of 6 people, randomized by blocking method

Settings and conduct
Samples will be selected from pregnant women referring to health centers in Ahvaz by available sampling method. Those who score on the Spielberger Anxiety Inventory are selected. Samples are randomly divided into sixteen blocks of six and are assigned to intervention and control groups. In the intervention program, individuals are divided into groups of five or less.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Pregnant women with at least a second abdomen, at least one experience of preterm labor earlier than 37 weeks of gestation, gestational age 10 to 28 weeks with an anxiety score above the Spielberger Anxiety Questionnaire (score 43 and above for anxiety Manifest and score 46 and above for hidden anxiety), literate, wanting to be pregnant, no history of using psychiatric drugs and hospitalization due to psychiatric problems, no history of infertility and recurrent miscarriage, no doctor advising to rest Absolute.
Exclusion criteria: Conditions that affect the physiological state of the mother, such as diabetes mellitus, maternal indications for termination of pregnancy (severe preeclampsia, placental abruption, placenta previa with active bleeding), receiving psychotherapy.

Intervention groups
In the intervention group, in addition to receiving routine pregnancy care, women also participate in group sessions of 8 to 12 people based on mindfulness counseling. In the control group, women receive only routine pregnancy care.

Main outcome variables
Anxiety of pregnant women with a history of preterm labor

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220511054815N1**
Registration date: **2022-05-14, 1401/02/24**
Registration timing: **prospective**

Last update: **2022-05-14, 1401/02/24**
Update count: **0**

Registration date
2022-05-14, 1401/02/24

Registrant information

Name
Sahar Mohammadikhass

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3373 8331

Email address
s.mohammadikhass@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-10, 1401/03/20

Expected recruitment end date
2022-10-12, 1401/07/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Mindfulness-based counseling on Pregnant women with anxiety disorders experience of Preterm birth

Public title
The Effect of Mindfulness-based counseling on Pregnant women with anxiety disorders experience of Preterm birth

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women with at least a second pregnancy, at least one experience of preterm labor earlier than 37 weeks of gestation, gestational age 10 to 28 weeks with an anxiety score above the Spilberger Anxiety Questionnaire (43 and above for overt anxiety and 46 and Higher for latent anxiety), literate, wanting to be pregnant, no history of using psychiatric drugs and hospitalization due to psychiatric problems, no history of infertility and recurrent miscarriage, no doctor advising to rest completely.

Exclusion criteria:
Conditions that affect the physiological state of the mother, such as diabetes mellitus, maternal indications for termination of pregnancy (severe preeclampsia, placental abruption, placenta previa with active bleeding), unwillingness to participate in further study, receiving psychotherapy.

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples are randomly divided into sixteen blocks of six and are assigned to intervention and control groups. In the intervention program, individuals are divided into groups of five or less. A random sequence of blocking is assigned to a specific person outside the research team and assigns each mother to one of two intervention or control groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

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
Golestan Ave, Ahvaz Jundishapur University of Medical Science, Nursing and Midwifery School, Midwifery Department

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Approval date
2022-05-10, 1401/02/20

Ethics committee reference number
IR.AJUMS.REC.1401.054

Health conditions studied

1

Description of health condition studied
Anxiety of pregnant women with a history of preterm labor

ICD-10 code
F06.4

ICD-10 code description
اضطراب مادران باردار دارای سابقه زایمان زودرس

Primary outcomes

1

Description
Anxiety score of pregnant women in Spielberger Anxiety Questionnaire

Timepoint
Completion of Spielberger Anxiety Questionnaire before and after the intervention

Method of measurement
Spielberger Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Pregnant women with moderate to

high anxiety scores receive 8 sessions of mindfulness-based group counseling for 8 consecutive weeks. The number of people in groups is 5 and the duration of each session will be about 120 minutes. Each session has an educational purpose and during the session, they perform mindfulness exercises. Homework is also recommended for women to practice mindfulness in everyday events.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Ahwaz city health centers

Full name of responsible person
Sahar Mohammadikhass

Street address
Golestan Ave, Ahvaz Jundishapur University of Medical Science, Nursing and Midwifery School, Midwifery Department

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s.mohammadikhass@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Sahar Mohammadikhass

Street address
Golestan Ave, Ahvaz Jundishapur University of Medical Science, Nursing and Midwifery School, Midwifery Department

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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
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
Sahar Mohammadikhass

Position
midwife

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Golestan Ave, Ahvaz Jundishapur University of Medical Science, Nursing and Midwifery School, Midwifery Department

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Sahar Mohammadikhass

Position
midwife

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

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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

Undecided - It is not yet known if there will be a plan to make this available