Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison between the effect of Doing Yoga exercises and Mindfulness-Based Stress Reduction (MBSR) counseling on the Index and consequences of pregnancy in pregnant women after the twentieth week

Protocol summary

Study aim

- Comparison of Demographic variables in three groups of Yoga, Mindfulness-based stress reduction counseling and Control group before the intervention - Comparison of the mean score of pregnancy outcomes in three groups of Yoga, Mindfulness-based stress reduction counseling and Control group before the intervention - Comparison of the mean score of pregnancy outcomes in three groups of Yoga, Mindfulness-based stress reduction counseling and Control group after the intervention - Comparison of the mean score of pregnancy outcomes in the Yoga group before and after the intervention - Comparison of the mean score of pregnancy outcomes in Mindfulness-based stress reduction counseling group before and after the intervention

Design

Clinical trial will be with three groups (Two intervention groups and one control group).150 pregnant women, will be selected by block randomization and 50 people will be placed in each group.

Settings and conduct

The randomized clinical trial will be performed on 150 pregnant women referring to health centers in Kerman in 2022. They will be divided into 3 groups of 50 people.(Yoga, Mindfulness-based stress reduction counseling, Control). Data will be collected before the intervention, after the intervention and two weeks after the intervention, and after delivery through the pregnancy outcomes questionnaire.

Participants/Inclusion and exclusion criteria

Pregnant women after the twentieth week referred to Kerman health centers,2022

Intervention groups

In the yoga intervention group, Yoga exercises will be performed virtually for three weeks.(Three sessions per week). In the Mindfulness-based stress reduction counseling intervention group, the counseling will be performed virtually for three weeks.(Two sessions per week) In the control group, they will receive routine care.

Main outcome variables

Consequences of pregnancy such as Preeclampsia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170504033812N3**
Registration date: **2021-12-26, 1400/10/05**
Registration timing: **prospective**

Last update: **2021-12-26, 1400/10/05**
Update count: **0**

Registration date

2021-12-26, 1400/10/05

Registrant information

Name

Shahrzad Zolala

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 23871

Email address

zolala@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-01, 1400/10/11

Expected recruitment end date

2023-01-01, 1401/10/11

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison between the effect of Doing Yoga exercises and Mindfulness-Based Stress Reduction (MBSR) counseling on the Index and consequences of pregnancy in pregnant women after the twentieth week

Public title
Comparison between the effect of Doing Yoga exercises and Mindfulness-Based Stress Reduction (MBSR) counseling on the Index and consequences of pregnancy
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Being pregnant Having complete physical and mental health (absence of gastrointestinal, heart or other underlying diseases) Literacy to the extent of reading and writing Having a single, normal, live, uncomplicated pregnancy and maintaining it until the end of the study Women in the age range of 18 to 35 years Willingness to participate in the study
Exclusion criteria:
Loss of pregnancy Reluctance to continue participating in the study
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: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
150 pregnant women will be selected by Permuted block randomization. There will be 50 woman in each group. Eventually, there will be 45 pregnant women in each group considering the probability of a sample loss.
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
ethical committee of Kerman University of Medical Sciences
Street address
Jahad Blvd. Ebn Sina Avenue, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7619813159
Approval date
2021-12-16, 1400/09/25
Ethics committee reference number
IR.KMU.REC.1400.537

Health conditions studied

1

Description of health condition studied
Gestational diabetes, Preeclampsia, Pre-term, Post-term, Hypothyroidism, Cesarean section, Oligohydramnios, premature rupture of membranes
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Gestational diabetes, Preeclampsia, Pre-term, Post-term, Hypothyroidism, Cesarean section, Oligohydramnios, premature rupture of membranes, Depression
Timepoint
Before the intervention, immediately after the intervention, two weeks after the intervention and after delivery
Method of measurement
Pregnancy Outcome Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Women will do yoga exercises including movements such as preliminary relaxation of the body and breathing techniques, safe asana in the supine position, deep relaxation with guided imagery, pranayama and meditation using mental imagery and gentle song for three weeks (three sessions per week).

Yoga exercises will be done virtually by presenting a video by the specialist (having a valid certificate).

Category

Prevention

2

Description

Intervention group: Counseling with a mindfulness-based stress reduction approach in women will be conducted for three weeks (two sessions per week) in the form of six virtual two-hour sessions. Mindfulness exercises will be performed virtually by a trained and certified person.

Category

Prevention

3

Description

Control group: Routine interventions

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour hospital

Full name of responsible person

Haniye Soltaninegad

Street address

Afzalipour Educational and Medical Center,Imam Khomeini Highway, next to Shahid Bahonar University

City

Kerman

Province

Kerman

Postal code

7616913355

Phone

+98 34 3132 8000

Email

afzalipour@kmu.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Kerman University of Medical Sciences, Deputy of research and technology

Street address

Ebn-e-Sina St.,Jahad Blvd., Kernan,Iran

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7619813159

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+98 34 3226 3855

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induniv@kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Shahrzad Zolala

Position

aStudent Research Committee, Razi faculty of Nursing and Midwifery, Kerman University of Medical Sci

Latest degree

Master

Other areas of specialty/work

Midwifery

Street address

Kerman University of Medical Sciences,Medical University Campus,Haft-Bagh Highway, Kerman, Iran

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Kerman

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Email

zolala@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Shahrzad Zolala

Position

Student Research Committee, Razi faculty of Nursing and Midwifery, Kerman University of Medical Scie

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

Part of the data, such as information about the main outcome can be shared.

When the data will become available and for how long

Start the access period at 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

In case of citation to the article

From where data/document is obtainable

shahrzad.zolala@gmail.com

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

The files will be sent within one month after reading the email. Email: shahrzad,zolala@gmail.com

Comments