

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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

Shahzad 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

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+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

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

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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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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**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Kerman University of Medical Sciences

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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**