

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jul 2026

### Evaluating effectiveness of Mindfulness-based Counseling on Pregnancy Concerns and Anxiety

#### Protocol summary

##### Study aim

Determining the effectiveness of mindfulness-based counseling on pregnancy concerns and anxiety in primi gravidarum.

##### Design

Two arm parallel group randomized trial by blocking method with 30 people in each group

##### Settings and conduct

Sampling by multi-stage quotas, from Comprehensive Health centers from one of the areas of Mashhad, 10 samples were randomly selected from the list of pregnant women of that center that meets the entering criteria, and by calling them, invited to the health center for further examination and consent.

##### Participants/Inclusion and exclusion criteria

being within 12 to 24 weeks of pregnancy, having a singleton pregnancy, lack of a present or a history of psychiatric illness or chronic diseases in pregnancy, lack of high risk pregnancy items, Non-use of psychiatric drugs in a recent year, Non-use of drugs and psychotropic substances, Non-attendance at Yoga classes, Mindfulness and Mind Management in the past 6 months

##### Intervention groups

Women in the intervention group, in addition to receiving usual prenatal care, also participate in 8-12 people mindfulness-based counseling group. Women in the control group, only receive the usual prenatal care.

##### Main outcome variables

Anxiety and worry of pregnant mothers

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190206042641N1**

Registration date: **2019-07-03, 1398/04/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-07-03, 1398/04/12**

Update count: **0**

##### Registration date

2019-07-03, 1398/04/12

##### Registrant information

###### Name

Reyhaneh Abbasi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 3239 5054

###### Email address

abbasir911@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-29, 1398/03/08

##### Expected recruitment end date

2019-09-01, 1398/06/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating effectiveness of Mindfulness-based Counseling on Pregnancy Concerns and Anxiety

##### Public title

Evaluating effectiveness of Mindfulness-based Counseling on Pregnancy Concerns and Anxiety

##### Purpose

Education/Guidance

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

being Iranian and Persian speaking being satisfactory and interesting in participating in the research being her first pregnancy being within 12 and 24 weeks of pregnancy being a singleton pregnancy. getting 10 points of 6-item Kessler questionnaire at least

**Exclusion criteria:**

Having high risk pregnancy items Suffering from any chronic illnesses during pregnancy Participate in yoga classes, mindfulness and mind management in the last 6 months Use of psychiatric drugs in a recent year Use Drug and psychotropic substances Having a history of psychiatric illness

**Age**

From **18 years** old to **45 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is done by blocking method to balance the number of specimens assigned to each of the studied groups. In this way, the size of the blocks can be constant or variable. In this research, we used blocks with 4 equal numbers. Unit of randomization is individual. Random Block Sequencing Website have been used for randomization. The random sequence of locking is given to a specific person outside the research team and each mother assigns to either intervention or control group according to the time of arrival and random sequence.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Sampling will be done from specific health centers of 3 poor, medium and high socioeconomic regions of Mashhad.

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shahrood University of Medical Sciences

**Street address**

Shahrood University of Medical Sciences, 7th of Tir

square

**City**

Shahrood

**Province**

Semnan

**Postal code**

7394736147

**Approval date**

2019-05-08, 1398/02/18

**Ethics committee reference number**

IR.SHMU.REC.1398.011

**Health conditions studied**

**1**

**Description of health condition studied**

anxiety in pregnant women

**ICD-10 code**

F06.4

**ICD-10 code description**

Anxiety disorder due to known physiological condition

**2**

**Description of health condition studied**

worry in pregnant women

**ICD-10 code**

R45.82

**ICD-10 code description**

Worries

**3**

**Description of health condition studied**

Mindfulness-based counseling

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

Anxiety Score of Pregnant Women in Wendenberg  
Pregnancy Anxiety Inventory

**Timepoint**

Completing Wendenberg Anxiety Inventory before, after and 1 month after intervention

**Method of measurement**

Pregnancy Related Anxiety Questionnaire (Wendenberg)

**2**

**Description**

Pregnant women's worry score by Prenatal Distress Questionnaire

**Timepoint**

Completing the Prenatal Distress Questionnaire before, after and 1 month after intervention

**Method of measurement**

Prenatal Distress Questionnaire

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: Pregnant women with high anxiety score, will receive 6 mindfulness-based counseling sessions within 6 consecutive weeks. The number of participation in each groups is 8 to 12 people, and the duration of each session will be about 90 minutes. Each session has an educational purpose and the participation practice Mindfulness exercises during the session. Also, homework is recommended for women to practice Mindfulness in everyday life.

### Category

Behavior

2

### Description

Control group: Pregnant women with high anxiety score, attend Preparation for Labor classes regularly, and no additional intervention will be done for this group. After 6 weeks, intended questionnaires will be completed again by the women.

### Category

N/A

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Center for Comprehensive Health Services

#### Full name of responsible person

Reyhaneh Abbasi

#### Street address

Sanabad St., Mashhad Town

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9185684538

#### Phone

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#### Fax

+98 51 3859 7313

#### Email

abbasir911@gmail.com

## Sponsors / Funding sources

1

### Sponsor

Name of organization / entity

Shahrood University of Medical Sciences

### Full name of responsible person

Mohammad Hasan Emamian

### Street address

7th of Tir square, Shahrood Town

### City

Shahrood

### Province

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### Postal code

3614773955

### Phone

+98 23 3239 6714

### Fax

+98 23 3239 4852

### Email

emamian@shmu.ac.ir

### Web page address

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Shahrood 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

Shahrood University of Medical Sciences

#### Full name of responsible person

Reyhaneh Abbasi

#### Position

Student

#### Latest degree

Bachelor

#### Other areas of specialty/work

Midwifery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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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