Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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
+98 51 3841 5001

Fax
+98 51 3859 7313

Email
abbasir911@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Mohammad Hasan Emamian

Street address
7th of Tir square, Shahrood Town

City
Shahrood

Province
Semnan

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
Shahroud 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
Shahroud University of Medical Sciences

Full name of responsible person
Reyhaneh Abbasi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Shahrood University of Medical Sciences, Haft e Tir Square

City
Shahrood

Province
Semnan

Postal code
7394736147

Phone
+98 23 3239 5054

Fax

Email
abbasir911@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Reyhaneh Abbasi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Shahrood University of Medical Sciences, Haft e Tir Square
City
Shahrood
Province
Semnan
Postal code
7394736147
Phone
+98 23 3239 5054
Fax
+98 23 3239 5009
Email
abbasir911@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Reyhaneh Abbasi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Shahrood University of Medical Sciences, Haft e Tir Square
City
Shahrood
Province
Semnan
Postal code
7394736147
Phone
+98 23 3239 5054
Fax
+98 23 3239 5009
Email
abbasir911@gmail.com

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