Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effectiveness of educational package of psychological care during pregnancy based on mindfulness on pregnancy anxiety, mother-fetus attachment, psychological empowerment and marital satisfaction of pregnant womens

Protocol summary

Study aim
To investigate the effectiveness of a mindfulness-based educational package for psychological care during pregnancy on pregnancy anxiety, mother-fetus attachment, psychological empowerment, and marital satisfaction

Design
Clinical trial with control group, with parallel groups, randomized and without blinding on 40 pregnant women

Settings and conduct
Primiparous pregnant women who refer to several obstetrician and gynecologist offices in District 1 of Mashhad Municipality and are selected and randomly assigned to two experimental and control groups based on the study inclusion criteria. Pre-test, training, post-test, and follow-up will be conducted 45 days after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Aged Between 20 to 35 years, The first pregnancy, between 2nd to 6th month of pregnancy, informed consent, no addiction, no psychiatric disorders, no medical and obstetric problems, no mental crisis
Exclusion criteria: The presence of obvious fetal abnormalities, Unwillingness or inability to participate in sessions

Intervention groups
Intervention group: The mindfulness-based prenatal psychological care educational package developed by the researcher will be held for primiparous pregnant women during 8 sessions of 90 minutes (two sessions per week) for 1 month. The content of the sessions on mental health and psychological care during pregnancy is based on mindful pregnancy for better management of this period. Mindfulness helps people live with less stress and anxiety by focusing on being in the present moment and becoming aware of thoughts, feelings, and experiences without judgment. Control group: In order to observe ethics in research, after the end of intervention, two educational sessions will be received

Main outcome variables
Pregnancy Anxiety؛ Mother-Fetus Attachment؛ Psychological Empowerment؛ Marital Satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200117046165N2**
Registration date: **2025-10-31, 1404/08/09**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-25, 1405/06/03**
Update count: **1**

Registration date
2025-10-31, 1404/08/09

Registrant information

Name
Narges Zarei

Name of organization / entity
The University of Allameh Tabatabaei

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-16, 1404/07/24
Expected recruitment end date
2025-11-15, 1404/08/24
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of educational package of psychological care during pregnancy based on mindfulness on pregnancy anxiety, mother-fetus attachment, psychological empowerment and marital satisfaction of pregnant womens

Public title
Investigating the effect of educational package of psychological care during pregnancy based on mindfulness on pregnancy
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Aged between 20 to 35 years The first pregnancy Being between the 2nd to 6th month of pregnancy Having at least a high school diploma Residing in Mashhad city Desired pregnancy Informed consent to participate in the research No addiction and not being treated for psychiatric disorders No medical and obstetric problems based on medical records (diabetes, blood pressure, previous miscarriage, etc.) No mental crisis such as separation and death of loved ones during the 6 months prior to the research No attendance at yoga and meditation classes
Exclusion criteria:
The presence of obvious fetal abnormalities Unwillingness or inability to participate in sessions Having other medical and psychiatric disorders
Age
From **20 years** old to **35 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization in this study will be based on a simple random method. Therefore, a random number is assigned to each patient by the table of random numbers, according to which if the number is odd, the patient will be in the intervention group, and if it is an even number, the patient will be in the control group
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
Ethics Committee of the Faculty of Medicine, Islamic Azad University
Street address
Faculty of Medicine, Mashhad Azad University, No 47, Sarab Bazarche, 14 Imam Khomeini
City
Mashhad
Province
Razavi Khorasan
Postal code
9133736351
Approval date
2025-04-16, 1404/01/27
Ethics committee reference number
IR.IAU.MSHD.REC.1404.018

Health conditions studied

1

Description of health condition studied
Pregnancy
ICD-10 code
Z34.8
ICD-10 code description
Supervision of other normal pregnancy

Primary outcomes

1

Description
Pregnancy Anxiety
Timepoint
Before the intervention, after the intervention, 45 days after the end of the intervention
Method of measurement
The Vandenberg Pregnancy Related Anxiety Questionnaire

2

Description
Mother-Fetus Attachment
Timepoint

Before the intervention, after the intervention, 45 days after the end of the intervention

Method of measurement

The Cranly Mother-Fetus Attachment Questionnaire

3

Description

Psychological Empowerment

Timepoint

Before the intervention, after the intervention, 45 days after the end of the intervention

Method of measurement

Kameda’s Prenatal Psychological Empowerment Scale

4

Description

Marital Satisfaction

Timepoint

Before the intervention, after the intervention, 45 days after the end of the intervention

Method of measurement

Enrich Marital Satisfaction Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Primiparous pregnant women will undergo the mindfulness-based prenatal psychological care educational package intervention developed by the researcher during 8 sessions of 90 minutes (two sessions per week) for 1 month. The content of the sessions is related to obtaining information about mental health and psychological care with a mindful pregnancy and performing mindfulness exercises to gain peace and better management of this period. Mindfulness helps people live with less stress and anxiety by focusing on being in the present moment and becoming aware of thoughts, feelings, and experiences without judgment. The summary of the content of each session is as follows: 1) Introduction to mindfulness and self-awareness during pregnancy 2) Body awareness, acceptance of the pregnancy experience, and connection with the fetus 3) Stress, anxiety, and emotion regulation management 4) Self-compassion, self-care, and reduction of rumination 5) Mindfulness in relationships, social support, and couple communication 6) Psychological preparation for childbirth and conscious exposure to pain 7) Mindfulness in parenting, newborn care, and the postpartum period 8) Conclusion, consolidation of skills, and a plan for continued practice

Category

Treatment - Other

2

Description

Control group: This group will not receive any intervention. In order to observe ethics in research, after the end of intervention, two educational sessions will be provided for this group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Maternity clinic

Full name of responsible person

Maryam Grigoryan

Street address

Unit 4, Second Floor, Platinum Building 2, Kohsangi 8

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Maryam.griguriyan@gmail.com

2

Recruitment center

Name of recruitment center

Mothers' Paradise Midwifery Consulting Center

Full name of responsible person

Maryam Bazshad

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Third floor, Iranian Building, Kohsangi 8

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3

Recruitment center

Name of recruitment center

Gynecologist's office of Dr. Zahra Mohsenian

Full name of responsible person

Zahra Mohsenian

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Fourth Floor, Sina Doctors Building, Aref Street 2

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4

Recruitment center
Name of recruitment center
Gynecologist's office of Dr. Parisa Najafi
Full name of responsible person
Parisa Najafi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mitra Zeratpisheh
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369789@iau.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad University, Mashhad Branch
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
Islamic Azad University
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Narges Zarei
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Student
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Latest degree
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Other areas of specialty/work
Psychology

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Email

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
No - There is not 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