

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Effect of mindfulness-based childbirth and parenting program education on psychological distress, mindfulness, and marital satisfaction of women in pregnancy and postpartum depression

Protocol summary

Study aim

Determining the impact of MbcP program on psychological distress, mindfulness and marital satisfaction of women during pregnancy and postpartum depression

Design

A randomized controlled clinical trial on 40 pregnant women. A table of random numbers was used for randomization

Settings and conduct

I refer to health centers and women's clinics in Kashan. And 40 pregnant women with a gestational age of 28 to 35 weeks who have other entry criteria are randomly selected and fill the questionnaires. And then I divide into two intervention and control groups. In the intervention group, the childbirth and parenting program based on mindfulness will be implemented. Techniques will be taught, It is practiced in class and homework will be given. In the control group, psychological topics such as understanding the child's brain and child development are taught.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women whose gestational age is between 28 and 35. Exclusion criteria: pregnant women who received other psychological treatments.

Intervention groups

Mindfulness-based meditation is taught in each 2-hour session of the MBCP program based on the Mindfulness-Based Childbirth and Parenting Training Guide; In addition, the participants are asked to practice meditation exercises using the guide booklets that are given to them, for thirty minutes a day, 6 days a week. Mindfulness training is fully compatible with the current knowledge of psycho-biological processes during pregnancy, childbirth, postpartum and breastfeeding. The control group will receive psychological training in 8 sessions of 2 hours.

Main outcome variables

Psychological distress score in dass21 questionnaire
Mindfulness score in Freiburg Questionnaire
Marital satisfaction score in Enrich questionnaire
Postpartum depression score in the Edinburgh Questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221018056222N1**
Registration date: **2022-11-22, 1401/09/01**
Registration timing: **prospective**

Last update: **2022-11-22, 1401/09/01**

Update count: **0**

Registration date

2022-11-22, 1401/09/01

Registrant information

Name

Hanieh Nasrollahizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-29, 1401/09/08

Expected recruitment end date

2023-01-30, 1401/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of mindfulness-based childbirth and parenting program education on psychological distress, mindfulness, and marital satisfaction of women in pregnancy and postpartum depression

Public title

Training of childbirth and parenting program based on mindfulness in pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1- Age 18 to 40 years 2- Gestational age between 28 and 35 weeks 3- No use of psychotherapeutic drugs in the last 6 months 4- No history of substance abuse or addiction 5- Lack of history of suicide 6- No psychotic disorders 7- No personality disorders 8- Education above middle school 9 - Willingness and informed consent to participate in a research project

Exclusion criteria:

1- History of hospitalization during pregnancy 2- Absence in more than 2 treatment sessions 3- Receiving other psychological treatments

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly (using random number table) in two groups (a treatment group and a control group). The type of study is semi-experimental with a pre-test and post-test with a 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 Kashan University of Medical Sciences

Street address

On The 3th kilometerof Ravan Road

City

Kashan

Province

Isfahan

Postal code

8715973474

Approval date

2020-09-01, 1399/06/11

Ethics committee reference number

IR.KASHAN.MEDNT.REC.1399.082

Health conditions studied**1****Description of health condition studied**

pregnant women

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Psychological distress score in dass21 questionnaire

Timepoint

Measuring psychological distress at the beginning of the intervention and 2 months later (after the end of the intervention) and after delivery

Method of measurement

dass21 questionnaire

2**Description**

Mindfulness score in Freiburg Questionnaire

Timepoint

Measuring Mindfulness at the beginning of the intervention and 2 months later (after the end of the intervention) and after delivery

Method of measurement

Freiburg Questionnaire

3**Description**

Marital satisfaction score in Enrich questionnaire

Timepoint

Measuring Marital satisfaction at the beginning of the intervention and 2 months later (after the end of the intervention) and after delivery

Method of measurement

Enrich questionnaire

4**Description**

Postpartum depression score in the Edinburgh Questionnaire

Timepoint

Measuring postpartum depression after childbirth

Method of measurement

Edinburgh Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Intervention group: Mindfulness-based meditation is taught in each 120-minute session of the MBCP program based on the guidelines for childbirth and parenting based on mindfulness; In addition, the participants are asked to practice meditation exercises using the guide booklets that are given to them, for thirty minutes a day, 6 days a week. Mindfulness training is fully compatible with the current knowledge of psychological processes during pregnancy, childbirth, postpartum and breastfeeding. Also, this program includes many types of skills to deal with the psychological and physical pain of childbirth, as well as awareness skills to deal with stress in daily life. MPCP's childbirth preparation program focuses on mindfulness-based meditation training and participants' commitment to homework. In addition to mindfulness training, the essential element of this course is to encourage a sense of participation among expectant parents in order to reduce the negative impact of social isolation on the mental health of new parents in the postpartum and early parenting period.

Category

Treatment - Other

2**Description**

Control group: Control group: Psychological education topics are taught during 8 2-hour sessions. Topics such as fetal and infant development, infantile games

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Women's clinics of Shahid Beheshti Hospital

Full name of responsible person

Abdollah Omid

Street address

The 3th kilometer of Ravand Road

City

Kashan

Province

Isfahan

Postal code

8715973474

Phone

+98 31 5544 3022

Email

info@kaums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Ahman Pirozmand

Street address

The 3th kilometer of Ravand Road

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Kashan

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Isfahan

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Email

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kashan 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**

Kashan University of Medical Sciences

Full name of responsible person

Hanieh Nasrollahizadeh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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

Kashan University of Medical Sciences

Full name of responsible person

Hanieh Nasrollahizadeh

Position

student

Latest degree

Bachelor

Other areas of specialty/work

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Email

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Person responsible for updating data**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Hanieh Nasrollahizadeh

Position**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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Except for personal information such as name and surname, the rest of the information can be shared.

When the data will become available and for how long

The access period starts 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

Permission is granted to use the data to perform meta-analyses.

From where data/document is obtainable

Email address: Hanieh.n2022@gmail.com Phone number: 09128828447

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

After requesting through email or phone number and consulting with the research supervisor, information will be given within a week.

Comments