Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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
Isfehan
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 psycho-biological 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 Omidi
Street address
The 3th kilometer of Ravand Road
City
Kashan
Province
Isfehan
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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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
Studend
Latest degree
Bachelor
Other areas of specialty/work
Psychology
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Person responsible for updating data

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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
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