Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Comparison of the Effectiveness of Mindfulness-Based Childbirth and Parenting Program and Cognitive-Behavioral Therapy on Pregnancy Anxiety, Birth Satisfaction, Fear of normal delivery, and Labor Pain in Primiparous Women

Protocol summary

Study aim
Determining the effectiveness of mindfulness-based delivery and parenting program on pregnancy anxiety, fear of natural childbirth, labor pain and delivery satisfaction in nulliparous pregnant women

Design
After entering the questionnaire, the participants completed the demographic information questionnaire and after obtaining written consent from both the pregnant woman and her husband and in the absence of her father, randomly divided into two experimental groups and control are assigned

Settings and conduct
The allocation randomization is simple and uses a random number table. Random allocation concealment will also be done using the central randomization method.

Participants/Inclusion and exclusion criteria
Primiparous and monogamous pregnant women fluent in Persian have a normal and low-risk pregnancy and in the last month of the second or first trimester of pregnancy. Tendency to have a normal birth in a hospital Age 18 years and above Ability to spend at least 12 weeks research period BMI ≤ 30.1 in the first two months of pregnancy No history / current presence of severe psychiatric illness (psychotic disorders, mental disabilities, other disorders leading to hospitalization or use of psychiatric drugs) or alcohol or drug use, Lack of experience doing continuous mind-body exercises Exclusion criteria include converting the pregnancy to a high-risk pregnancy, having the intention and plan to have a cesarean section after entering the plan, requiring specific medical conditions of the mother or fetus that require termination of pregnancy before 37 weeks. Having or needing to take psychiatric medication or starting to use alcohol and drugs after entering the course

Intervention groups
Cognitive-behavioral therapy group Mindfulness-based delivery and parenting program group

Main outcome variables
Pregnancy anxiety - Fear of childbirth - Labor pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201009048974N1**
Registration date: **2021-01-25, 1399/11/06**
Registration timing: **retrospective**

Last update: **2021-01-25, 1399/11/06**
Update count: **0**

Registration date
2021-01-25, 1399/11/06

Registrant information

Name
Maryam Bakhtiari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2020-10-26, 1399/08/05

Expected recruitment end date

2020-11-25, 1399/09/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of the Effectiveness of Mindfulness-Based Childbirth and Parenting Program and Cognitive-Behavioral Therapy on Pregnancy Anxiety, Birth Satisfaction, Fear of normal delivery, and Labor Pain in Primiparous Women

Public title

The Comparison of the Effectiveness of Mindfulness-Based Childbirth and Parenting Program and Cognitive-Behavioral Therapy on Pregnancy Anxiety, Birth Satisfaction, Fear of normal delivery, and Labor Pain in Primiparous Women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

pregnant Women Primiparous Women

Exclusion criteria:

psychosis Hi risk pregnancy Taking psychiatric medication

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

After entering the questionnaire, the participants completed the demographic information questionnaire and after obtaining written consent from both the pregnant woman and her husband and in the absence of her father, randomly divided into two experimental groups (cognitive behavioral therapy and delivery and parenting program based on Mindfulness) and control are assigned. The allocation randomization is simple and uses a random number table. Random allocation concealment will also be done using the central randomization method. After assigning individuals to the groups, a pretest is performed for the variables of labor pain, pregnancy anxiety and fear of normal delivery for individuals in both groups. Then, mindfulness and cognitive-behavioral delivery and parenting programs are implemented for the experimental 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

Research Ethics Committee of School of Medicine - Shahid Beheshti University of Medical Sciences

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

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Approval date

2019-09-24, 1398/07/02

Ethics committee reference number

IR.SBMU.MSP.REC.1398.665

Health conditions studied

1

Description of health condition studied

Pregnancy Anxiety, Birth Satisfaction, Fear of normal delivery, and Labor Pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pregnancy Anxiety Score in PRAQ Questionnaire

Timepoint

Before intervention and after intervention

Method of measurement

PRAQ Questionnaire

2

Description

Fear score of natural childbirth in Vijma childbirth expectation questionnaire

Timepoint

Before intervention and after intervention

Method of measurement
Vijma childbirth expectation questionnaire

3

Description
Mindfulness score in the Five Facet Mindfulness Questionnaire and Multidimensional Assessment of Interoceptive Awareness questionnaire
Timepoint
Before intervention and after intervention
Method of measurement
Five Facet Mindfulness Questionnaire and Multidimensional Assessment of Interoceptive Awareness questionnaire

4

Description
Visual analog scale of labor pain
Timepoint
during labor
Method of measurement
Score zero to 10 on the visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Cognitive-behavioral therapy group. Cognitive-behavioral educational intervention in this study was based on appropriate cognitive-behavioral methods to reduce anxiety in pregnant women and programs set by the Ministry of Health during 12 sessions of 90 minutes and twice a week. It should be noted that each intervention session is organized by providing assignments and giving feedback to sample members and performing appropriate exercises, as well as a review of previous sessions.
Category
Treatment - Other

2

Description
Intervention group: Mindfulness-based childbirth and parenting program. Participants begin MBCP in the late second or early third trimester and are asked to listen to meditation guide CDs at home 30 minutes a day, 6 days a week. Formal mindfulness meditation instructions include sitting meditation, body monitoring, mindfulness pug, and couple meditation in sessions. These techniques are adapted to cover the mental and physical aspects of pregnancy.
Category
Treatment - Other

3

Description
Control group: General education of pregnancy and childbirth
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Ghiasi Hamed
Street address
Velenjak St. , Shahid Chamran Highway, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Maryam Bakhtiari
Position
Associate Professor
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
Not applicable
Data Dictionary
Not applicable