Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Mindfulness Based on Childbirth Program on Fear of Childbirth and Depression in Pregnant Women

Protocol summary

Study aim

To determine the effect of a mindfulness based on childbirth program on fear of childbirth and depression in pregnant women

Design

The clinical trial has intervention and control groups, randomly assigned in a parallel-group, single-blind design.

Settings and conduct

This study will be conducted at Shahid Akbarabadi Hospital with two groups (intervention and control), using a four-block randomization method in a single-blind design (statistical analyses). The study will compare the effect of a mindfulness-based childbirth preparation program on fear of childbirth and depression in pregnant women before and immediately after the intervention in both groups.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Pregnant women over 18 years old, with a singleton pregnancy (15–22 weeks), perceived stress score ≥ 28, normal BMI, Iranian ethnicity, able to attend all sessions, literate in Persian, and with adequate hearing, speaking, and comprehension abilities.
Exclusion Criteria: Before the study: Alcohol or drug abuse, prior mindfulness experience, major medical or psychiatric disorders, history of fetal anomalies, or use of certain medications (anticonvulsants, antidepressants, thyroid hormones, corticosteroids). During the study: Missing >2 sessions, withdrawal, fetal anomalies, obstetric complications, major adverse life events, or development of psychiatric disorders.

Intervention groups

Intervention group (mindfulness based on childbirth program) and control group (routine antenatal care)

Main outcome variables

Fear of childbirth and Depression

General information

Reason for update

Registration of the final study results following completion of the clinical trial.

Acronym

IRCT registration information

IRCT registration number: **IRCT20250801066718N1**
Registration date: **2025-08-16, 1404/05/25**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-06, 1405/07/14**
Update count: **1**

Registration date

2025-08-16, 1404/05/25

Registrant information

Name

Badriyeh Daniyali

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 917 429 7246

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-14, 1404/05/23

Expected recruitment end date

2025-12-22, 1404/10/01

Actual recruitment start date

2025-08-14, 1404/05/23

Actual recruitment end date

2025-09-23, 1404/07/01

Trial completion date

empty

Scientific title
The Effect of Mindfulness Based on Childbirth Program on Fear of Childbirth and Depression in Pregnant Women

Public title
Mindfulness Program on Fear of Childbirth and Depression in Pregnancy

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Perceived Stress Score equal to or greater than 28 Singleton pregnancy Gestational age between 15 and 22 weeks Maternal age above 18 years Ability to attend all educational sessions Ability to read and write in Persian Iranian ethnicity of the mother Normal maternal body mass index (BMI) Full consciousness and adequate hearing and speaking ability to receive training and respond to questions

Exclusion criteria:
Alcohol and drug addiction Any history of mindfulness training or meditation History of previous fetal anomaly History of maternal treatment with anticonvulsants, antidepressants, thyroid hormones, and cortisone History or current presence of medical disorders History of serious psychiatric disorders, including psychotic disorders, bipolar disorder, depression, and medication use confirmed by a physician (based on the medical history obtained by the researcher from the pregnant mother and the information documented in her medical record).

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **94**
Actual sample size reached: **87**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible participants will be continuously enrolled in the study. They will then be randomly assigned in blocks of four to either the intervention group (mindfulness based on childbirth program) or the control group (routine prenatal education and care). The randomization sequence will be generated using the SealedEnvelope website.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the data analyst will be blinded to the group allocation (intervention or control) and will receive only coded data for statistical analyses.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Iran University of Medical Sciences

Street address
Deputy of Research and Technology, Central Headquarters Building, Iran University of Medical Sciences, next to Milad Tower, Hemmat Highway, Tehran

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2024-08-11, 1403/05/21

Ethics committee reference number
IR.IUMS.REC.1403.394

Health conditions studied

1

Description of health condition studied
Perinatal depression

ICD-10 code
F53.0

ICD-10 code description
Mild mental and behavioural disorders associated with the puerperium, not elsewhere classified

2

Description of health condition studied
Fear of Childbirth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Depression score in the Edinburgh Questionnaire

Timepoint
Before the intervention and immediately after the intervention

Method of measurement
Edinburgh Postnatal Depression Scale (EPDS)

2

Description
Fear of Childbirth score in the Wijma Questionnaire
Timepoint
Before the intervention and immediately after the intervention
Method of measurement
Wijma delivery expectancy questionnaire (W-DEQ (A))

3

Description
Mindfulness score on the Five Facet Mindfulness Questionnaire
Timepoint
Before the intervention and immediately after the intervention
Method of measurement
Five Facet Mindfulness Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
This study was designed as an educational–psychological intervention with an intervention group (mindfulness based on childbirth program) and a control group (routine prenatal care and education) in 2025 . At the first visit, all mothers (both control and intervention groups) in the 15th–22nd weeks of pregnancy, or during gatherings in the waiting room, were provided with the necessary information about the study, the existing groups, and its objectives.Mothers in the intervention group, who were randomly selected during the visit, could voluntarily choose their preferred session times according to the schedule if they were willing to participate. After signing the informed consent form and receiving the necessary explanations, the Perceived Stress Questionnaire was completed by the intervention group. If the score obtained from the questionnaire was above 28 and the inclusion criteria were met, the mother was enrolled in the intervention.The measurement tools included the Wijma Delivery Expectancy/Experience Questionnaire, the Edinburgh Postnatal Depression Scale, and the Five Facet Mindfulness Questionnaire. The scores obtained from these questionnaires were assessed and recorded before the intervention.In the intervention group, women were divided into subgroups of 7-10 participants, each consisting of both multiparous and primiparous women. Eligible mothers in the intervention group attended in-person mindfulness sessions once a week for a total of eight sessions, and the data were documented in the relevant checklist. The intervention was delivered in person, once a week, for three hours per session, over eight consecutive weeks. Session 1: Introduction to mindfulness, physiology of pregnancy and childbirth, and discussion of the culturally meaningful value of present-moment awareness. Raisin meditation practice.Session 2: Recognising bodily sensations, thoughts and emotions, the physiological stress response (fight-or-flight), responding to pregnancy-related fears, and practising patience when facing pregnancy-related challenges. Body scan practice.Session 3: Coping with pain and discussion of the culturally meaningful value of trust in God as a supportive coping resource. Ice exercise and mindful breathing during discomfort.Sessions 4–6: Understanding the childbirth process and labour pain, applying mindfulness to unpleasant sensations and uncertainty, and recognising and using emotional and practical support from family members. Yoga, mindful family inquiry about fear and joy, and sitting meditation.Session 7: Integrating mindfulness into childbirth and early parenting and cultivating self-compassion. Loving-kindness meditation.Session 8: Reviewing the entire course and practising previously learned mindfulness skills. Continued independent mindfulness practice, applying mindfulness to daily activities and childbirth-related experiences, and daily gratitude journaling.
Category
Other

2

Description
Control group: At the first visit, all mothers (both control and intervention groups) in the 15th–22nd weeks of pregnancy, or during gatherings in the waiting room, were provided with the necessary information about the study, the existing groups, and its objectives. The control group received only routine prenatal care and education. Mothers in the control group who were randomly selected during the visit, after completing the informed consent form and receiving the necessary explanations, completed the Perceived Stress Questionnaire. If the score obtained from the Perceived Stress Questionnaire was above 28 and the inclusion criteria were met, the mother was enrolled in the study.The measurement tools included the Wijma Delivery Expectancy/Experience Questionnaire, the Edinburgh Postnatal Depression Scale, and the Five Facet Mindfulness Questionnaire, which were completed by the control group mothers before the start of the intervention and again eight weeks later. The obtained scores from these questionnaires were then analyzed.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbarabadi Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Dr. Majid Safa – Vice President for Research and Technology
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Self-funded by the researcher
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

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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
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

Trial results

Please tick if results have been published
Yes
Summary result posting date
2026-10-06, 1405/07/14
Table of baseline comparison

Pregnant women	Intervention group (n=42)	Control group (n=45)	*p*
Age M (SD)	33.26 (7.74)	30.78 (5.89)	0.09 [illegible]
Married ,n(%)	42 (100)	45 (100)	-
Duration of Marriage M (SD)	10.21 (6.56)	7.73 (5.88)	0.06 [illegible]
Education level, n(%)			0.68 [illegible]
University education or higher	10 (23.8)	8 (17.8)	
High school or lower	32 (76.2)	37 (82.2)	
Employment, n(%)			0.66 [b]
Yes	3 (7.1)	2 (4.4)	
No	39 (92.9)	43 (95.6)	
Income, n(%)			0.11 [illegible]
Less than IRR 150,000,000	32 (76.2)	40 (88.9)	
More than IRR 150,000,000	10 (23.8)	5 (11.1)	
Parity, n(%)			0.69 [illegible]
Nulliparous	16 (38.1)	19 (42.2)	
Multiparous	26 (61.9)	26 (57.8)	
Previous Mode of birth°			0.57 [illegible]
Vaginal	10 (38.5)	12 (46.2)	
Cesarean	16 (61.5)	14 (53.8)	
History of Miscarriage(s)			0.56 [illegible]
Yes	9 (21.4)	12 (26.7)	
No	33 (78.6)	33 (73.3)	
History of Infertility, n(%)			0.51 [b]
Yes	6 (14.3)	4 (8.9)	
No	36 (85.7)	41 (91.1)	
Pregnancy Complications, n(%)			0.26 [b]

Yes	2 (4.8)	6 (13.3)	
No	40 (95.2)	39 (86.7)	
Partners			
Age, M (SD)	37.33 (6.92)	35.09 (5.97)	0.10 □
Education level, n(%)			0.19 □
University education or higher	10 (23.8)	6 (13.3)	
High school or lower	32 (76.2)	39 (86.7)	
Employment, n(%)			0.99 [b]
Yes	41 (97.6)	43 (95.6)	
No	1 (2.4)	2 (4.4)	
M: Mean; SD: Standard Deviation; IRR: Iranian Rial.[a] Chi-Square test; [b] Fisher's Exact Test; □ Independent t test; ° Numbers and percentages for Previous Mode of birth are based only on multiparous women (n=26 in intervention, n=26 in control). p ≤ .05 was considered significant.			

Participant flow diagram

CONSORT 2025 Flow Diagram	
Enrolment	
Assessed for eligibility	n=215
Excluded	n=121
Not meeting inclusion criteria	n=86
Declined to participate	n=14
Other reasons	n=21
Randomised	n=94
Allocation	
Intervention group (n=47)	
Received allocated intervention	n=47
Did not receive allocated intervention	n=0
Control group (n=47)	
Received routine antenatal care	n=47
Did not receive routine antenatal care	n=0
Follow-Up: Intervention group	
Discontinued intervention	n=3: personal reasons
Lost to follow-up for primary outcome	n=2: No response
Follow-Up: Control group	
Discontinued intervention	n=0
Lost to follow-up for primary outcome	n=2: No response
Analysis: Intervention group	
Analysed for primary outcome	n=42
Excluded from analysis	n=0
Analysis: Control group	
Analysed for primary outcome	n=45
Excluded from analysis	n=0

Table of variable outcomes' results

Analysis of Covariance (ANCOVA) for Between-Group Differences on Post-intervention (T1) Scores, Controlling for Pre-intervention (T0) Scores								
Variable	**Group**	**N**	**Post-Test M (SD)**	**Adjusted Mean (SE)**	***F* (1, 84)**	***p***	**Adjusted Mean Difference (95% CI)**	***η2p***
W-DEQ	Intervention	42	34.95 (21.16)	34.74 (2.84)	16.19	<0.001	-15.87 [-23.71, -8.03]	0.162
	Control	45	50.40 (22.07)	50.60 (2.74)				
EPDS	Intervention	42	5.71 (4.54)	6.02 (0.56)	7.90	0.006	-2.20 [-3.76, -0.64]	0.086
	Control	45	8.51 (4.42)	8.22 (0.54)				
FFMQ	Intervention	42	142.26 (22.19)	141.18 (2.25)	8.90	0.004	9.35 [3.12, 15.58]	0.096
	Control	45	130.82 (20.25)	131.83 (2.18)				
Note: Adjusted means (Estimated Marginal Means) are reported controlling for the respective pre-intervention (T0) score as the covariate. M: Mean; SD: Standard Deviation; SE: Standard error; CI: Confidence Interval; η^2: Partial eta-squared (effect size). W-DEQ: Wijma Delivery Expectancy/Experience Questionnaire; EPDS: Edinburgh Postnatal Depression Scale; FFMQ: Five Facet Mindfulness Questionnaire. Adjusted Mean Difference represents the difference between the Intervention group and the Control group (Intervention - Control). $p \leq .05$ was considered significant.								

Descriptive Statistics and Paired t-Test Results for Within-Group Changes from Pre-intervention (T0) to Post-intervention (T1)								
Variable	**Group**	**N**	**T0 M (SD)**	**T1 M (SD)**	**Differences (SD)[a]**	***t* (df)**	***p***	**Cohen's *d***
W-DEQ	Intervention	42	47.64 (24.17)	34.95 (21.16)	−12.69 (18.89)	4.35 (41)	<0.001	−0.67
	Control	45	46.80 (22.57)	50.40 (22.07)	3.60 (24.06)	1.00 (44)	0.321	0.15
EPDS	Intervention	42	9.14 (5.35)	5.71 (4.54)	−3.43 (4.07)	5.44 (41)	<0.001	−0.84
	Control	45	10.24 (4.49)	8.51 (4.42)	−1.73 (4.40)	2.64 (44)	0.011	−0.39
FFMQ	Intervention	42	134.69 (20.70)	142.26 (22.19)	7.57 (15.58)	3.15 (41)	0.003	0.49
	Control	45	132.11 (17.60)	130.82 (20.25)	−1.29 (14.34)	0.60 (44)	0.550	−0.09
N, number of participants; SD, standard deviation; df, degrees of freedom; T0, pre-test; T1, post-test. W-DEQ, Wijma Delivery Expectancy/Experience Questionnaire; EPDS, Edinburgh Postnatal Depression Scale; FFMQ, Five Facet Mindfulness Questionnaire. [a]Mean difference = T1 post-intervention score minus T0 pre-intervention score. *t* values are reported as absolute values; negative values indicate a decrease in scores (desirable for W-DEQ and EPDS), whereas positive values indicate an increase in scores (desirable for FFMQ). $p \leq .05$ was considered statistically significant.								

Table of adverse events

First publication date

empty

Abstract of published paper

At post-intervention assessment, participants in the intervention group had significantly lower fear of childbirth and depression scores and significantly higher mindfulness scores than those in the control group, after adjusting for baseline scores. The between-group differences were significant for fear of childbirth ($F(1,84)=16.19$, $p<0.001$, $\eta^2p=0.162$), depression ($F(1,84)=7.90$, $p=0.006$, $\eta^2p=0.086$), and mindfulness ($F(1,84)=8.90$, $p=0.004$, $\eta^2p=0.096$).