Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Effect of Mindfulness-Based Counseling on the Perception of Back Pain in Primiparous Pregnant Women

Protocol summary

Study aim

Primary Objective: To investigate the effect of mindfulness-based counseling on back pain perception in primiparous pregnant women. Secondary Objectives: To compare back pain intensity (VAS) and pain perception (McGill) between intervention and control groups before, immediately after, and 6 months post-intervention.

Design

A randomized controlled educational/counseling interventional trial with a parallel control group, single-blind, using block randomization on primiparous pregnant women in weeks 24 to 26 of gestation. Block randomization with block sizes of 4 and 6 was performed using R software, with allocation concealment via sequentially numbered, opaque, sealed envelopes. Sample size was calculated based on the primary objective, with 80% power and a significance level of 0.05.

Settings and conduct

The study is conducted in urban health centers in Khorramabad among primiparous women in weeks 24–26 with VAS 3–4. Participants are block-randomized (using R software) and allocated via SNOASE envelopes; the intervention group receives 6–7 sessions of 90-minute mindfulness counseling.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Primiparous women; in weeks 24–26 of pregnancy; have SIB electronic record in Khorramabad urban centers; VAS score 3–4; provide informed consent. Exclusion Criteria: No moderate back pain (VAS <3 or >4); no informed consent; outside weeks 24–26; not primiparous.

Intervention groups

Intervention Group: 6–7 group sessions of 90-minute mindfulness counseling (moment awareness, breathing, body scan, meditation, pain acceptance); Control Group: Standard prenatal care; session content provided as PDF at study end.

Main outcome variables

Primary Outcome: Change in total McGill Pain Questionnaire score. Secondary Outcomes: Change in VAS score; McGill sensory subscale; McGill affective subscale; McGill evaluative subscale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251017067664N1**
Registration date: **2025-11-03, 1404/08/12**
Registration timing: **prospective**

Last update: **2025-11-03, 1404/08/12**
Update count: **0**

Registration date

2025-11-03, 1404/08/12

Registrant information

Name

Forozan Morovati

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-12-01, 1404/09/10

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the Effect of Mindfulness-Based Counseling on the Perception of Back Pain in Primiparous Pregnant Women

Public title
Effect of Mindfulness-Based Counseling on Back Pain During Pregnancy
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Women are primiparous. They are in weeks 24 to 26 of pregnancy. They have an electronic health record in the SIB system at urban health centers in Khorramabad. They score 3 to 4 on the Visual Analog Scale (VAS) for pain. They provide informed consent to participate in the study. Singleton pregnancy
Exclusion criteria:
History of back pain before pregnancy History of chronic musculoskeletal or spinal diseases Presence of pregnancy complications such as high blood pressure, bleeding, or placenta previa History of chronic diseases such as diabetes or heart disease History of recurrent miscarriage or high-risk pregnancy Regular exercise before pregnancy Education or employment in psychology or counseling fields Employment in heavy work or continuous lifting of heavy objects Severe obesity (very high BMI) Diagnosed mental disorders or use of psychiatric medications
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
In this study, block randomization was used to allocate pregnant women to the intervention and control groups. The unit of randomization was individual, meaning each participant was separately assigned to one of the two groups. Block sizes of 4 and 6 were used to maintain balance in the number of participants across groups. The randomization sequence was generated using R statistical software. The allocation sequence was produced by the statistical consultant, and group codes (A and B) were randomly assigned. To prevent selection bias, sequentially numbered, opaque, sealed envelopes (SNOASE) were used. Each envelope contained the allocation code (A or B). After a qualified participant entered the study, the next envelope in numerical order was opened. Thus, the researcher remained unaware of the participant's group until the moment of allocation, ensuring full allocation concealment.
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 ofArak University of Medical Sciences
Street address
Shahid Shiroudi street
City
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Province
Markazi
Postal code
3819693345
Approval date
2025-09-07, 1404/06/16
Ethics committee reference number
IR.ARAKMU.REC.1404.180

Health conditions studied

1

Description of health condition studied
Backpain
ICD-10 code
M54.5
ICD-10 code description
Low back pain

Primary outcomes

1

Description
Change in total McGill Pain Questionnaire (MPQ) score from baseline to immediately post-intervention.
Timepoint
Baseline (pre-intervention), immediately after the last intervention session, and 6 months post-intervention.
Method of measurement
McGill Pain Questionnaire

2

Description

Change in total McGill Pain Questionnaire (MPQ) score from baseline to 6 months post-intervention.

Timepoint

Baseline (pre-intervention), immediately after the last intervention session, and 6 months post-intervention.

Method of measurement

McGill Pain Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: The intervention is developed based on the mindfulness techniques training protocol by Williams and Penman (2011) and consists of 8 group educational sessions lasting 90 minutes each (in groups of 10 individuals). The sessions are conducted by the researcher (who has completed a mindfulness-based counseling training course) in the training hall of urban comprehensive health centers in Khorramabad County. Training is delivered using techniques such as question-and-answer, role-playing, in-class and homework assignments, and is grounded in exercises including reflection, body scan, mindfulness meditation, and mindful breathing. The detailed content of each session is as follows:Session 1 (Introduction and Foundation):Introduction to the objectives, structure, and rules of the sessions;Administering pre-test (McGill Pain Questionnaire MPQ and Visual Analog Scale VAS);Presenting the history of each participant;Explaining the concepts of pregnancy, back pain, mindfulness, and its effects on life;Teaching deep breathing (focusing on inhalation and exhalation) with practical implementation;Emphasizing repetition of the exercise in each session;Obtaining feedback from participants;Emphasizing the importance of homework;Distributing specialized educational booklets for pregnant women.Session 2 (Practicing Presence in the Moment):Reviewing homework and obstacles (such as mind wandering);Emphasizing persistence in mindfulness practices;Teaching seated body scan (practical implementation);Teaching mindfulness in daily activities (mindful attention to routine tasks);Homework: Daily body scan practice and mindfulness in one simple activity.Session 3 (Living in the Moment):Reviewing homework;Exercises for seeing and hearing in the present moment (exercise "now – here");Performing the raisin eating exercise with full mindfulness;Repeating the seated body scan;Teaching mindful walking;Homework: Mindful walking practice and daily body scan.Session 4 (Stress Management):Reviewing homework;Defining stress and why negative memories are highlighted;Visualizing a pleasant event;Awareness of daily unpleasant events;Homework: Daily recording of one pleasant and one unpleasant event.Session 5 (Acceptance Without Judgment):Reviewing homework;Examining ways to avoid bad moods;Emphasizing non-attachment to positive and negative events;Performing the three-minute breathing exercise (space, body, breath);Homework: Daily three-minute breathing practice.Session 6 (Distinguishing Thoughts and Emotions):Reviewing homework;Distinguishing thoughts, emotions, and feelings (especially in pregnancy and childbirth);Expressing participants' thoughts and emotions in the pregnancy domain;Teaching mindful confrontation with negative thoughts;Practicing focus on breathing;Homework: Recording thoughts related to back pain and mindfulness practice.Session 7 (Pleasurable Activities):Reviewing homework;Performing body check exercise;Preparing a list of pleasurable activities for the coming week;Homework: Performing at least 3 pleasurable activities and recording their effect on pain.Session 8 (Consolidation and Closure):Reviewing homework and body scan;Overall review of all sessions and learned skills;Planning for continuing a mindful lifestyle;Adapting exercises to pregnancy conditions;Administering post-test (MPQ and VAS);Providing the complete session content in PDF format to the control group at the end of the study.

Category

Other

2

Description

Control Group: The control group receives no mindfulness-based educational or counseling intervention and is only under routine pregnancy care (including regular midwifery visits, weight and blood pressure monitoring, routine laboratory tests, and standard health center education on nutrition, physical activity, and pregnancy warning signs). The McGill Pain Questionnaire (MPQ) and Visual Analog Scale (VAS) are completed by the control group in three stages (before the start of the intervention, immediately after the completion of the 8 intervention sessions in the opposite group, and 6 months after the intervention). At the end of the study and after collecting the final data, the complete content of the 8 educational sessions (including booklets, exercises, and guided audio files) is provided in PDF format to the members of the control group to ensure ethical fairness and allow them to benefit from the intervention as well. No educational contact, group session, or homework is planned for the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorramabad Urban Health Centers

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Research Vice-Chancellery of Arak 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
Arak 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
Arak University of Medical Sciences

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Foroozan Morovati

Position
Student

Latest degree
Master

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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