Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of mindfulness training on the pain intensity of natural childbirth of primiparous women: A randomized controlled clinical trial study

Protocol summary

Study aim

Determining the effect of mindfulness training on the pain intensity of normal delivery of primiparous women covered by the Agh Qala health and treatment network, in 2024

Design

This study is a randomized clinical trial with a control group. The samples of this study will be selected using the information recorded in the electronic record of pregnant women in the Nab system (health information software). After receiving the informed consent, 76 eligible pregnant women will be assigned to the intervention (N=38) and control (N=38) groups using the block randomization method of 4 groups.

Settings and conduct

The study population includes The study population includes all primiparous pregnant women covered by comprehensive health services centers of urban and rural in Agh Qala.The samples include pregnant women eligible for the study. The place of conducting this research is in comprehensive health service centers and the measurement of pain intensity is done in Al Jalil Agh Qala Hospital. Midwives measuring pain intensity in the hospital and epidemiologists analyzing the results are blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Low-risk pregnancy, single fetus, desire for vaginal delivery Exclusion criteria: Reluctance to continue participating in the study, having a severe medical illness, participating in any individual or group psychotherapy classes during the study, terminating the pregnancy by cesarean section

Intervention groups

Intervention group: Mindfulness in 8 group counseling sessions Control group: Routine care and training

Main outcome variables

The intensity of labor pain, will be measured using VAS (visual analog Scale) during 3 times (patient's entry to the maternity ward, 7 to 8 cm dilatation, the beginning of the second stage of labor) by the midwife colleague of the maternity ward.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240620062188N1**
Registration date: **2024-07-09, 1403/04/19**
Registration timing: **prospective**

Last update: **2024-07-09, 1403/04/19**
Update count: **0**

Registration date

2024-07-09, 1403/04/19

Registrant information

Name

Akram Makin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-22, 1403/05/01

Expected recruitment end date

2025-07-23, 1404/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of mindfulness training on the pain intensity of natural childbirth of primiparous women: A randomized controlled clinical trial study

Public title

The effect of mindfulness training on labor pain

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women of reproductive age (10-54 years) Low risk pregnancy Single fetus, alive and healthy Being in the second trimester of pregnancy Desire for normal delivery

Exclusion criteria:

Passing mindfulness courses Participating in childbirth preparation classes High risk pregnancy including: preterm labor, placental abnormality, multiple births, the need for absolute rest prescribed by a midwife or doctor. The woman and her husband have a known mental illness, the use of psychiatric drugs or incurable physical diseases (cancers) and chronic diseases during the last two months. Use of drugs, psychedelics and alcohol Experiencing a severe stressful event within the past 3 months

Age

From **10 years** old to **54 years** old

Gender

Female

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants in this study will be assigned to two intervention (B) and control (A) groups using Block Randomization. In this way, using a dice that has 6 sides, the samples will be assigned to their groups. A number is written on each side, and each number is assigned to one of the blocks in the table, which shows its own state. Group A (routine care) and B (mindfulness training). The complete list of randomized blocks will be provided to the principal investigator by the study epidemiology consultant.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding in this study is single blinding. So that the pregnant woman knows which study group she will be in, but the investigator will not know the type of study group of the pregnant woman. The method of blinding will be in such a way that the midwife of labor part, who is not aware of the study process and the type of group of participants in the study, will measure the pain intensity of pregnant women on 3 occasions.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Golestan University of Medical Sciences

Street address

Toranj Building,10 Mehrgan, 6 Sayad Ave, Sayad Shirazi Blvd.

City

Gorgan

Province

Golestan

Postal code

4917965924

Approval date

2024-06-18, 1403/03/29

Ethics committee reference number

IR.GOUMS.REC.1403.129

Health conditions studied

1

Description of health condition studied

The effect of mindfulness training on the severity of labor pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

severity of labor pain

Timepoint

During 3 times (patient's entry to the maternity ward - 7 to 8 cm dilatation - beginning of the second stage of labor)

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
8 mindfulness group training sessions based on the protocol are held weekly for 90 minutes in the second trimester of pregnancy for 38 pregnant women by the researcher in person.
Category
Other

2

Description
Control group: routine care and training of comprehensive health service center
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
comprehensive health service center
Full name of responsible person
Asieh Sadat Baniaghil
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Sponsors / Funding sources

1

Sponsor
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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
Gorgan University of Medical Sciences
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

Contact
Name of organization / entity
Gorgan University of Medical Sciences
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Associate professor
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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