

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of mindfulness on labor pain in primiparous women

Protocol summary

Study aim

The effect of mindfulness on labor pain in primiparous women referred to Kashan Shahid Beheshti Hospital

Design

This study is a randomized controlled trial with parallel design. Sample size is 112 persons. Samples will be randomly assigned to control and intervention groups using 4-block design.

Settings and conduct

This study will be carried out at Kashan Shahid Beheshti Hospital. Pregnant women will be trained in delivery preparation classes. 6.8 -10 cm and episiotomy time in both groups will be assessed using pain ruler and McGill questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria are nulliparous, gestational age between 20-23 weeks, age 18-35 year, singleton pregnancy, having secondary school education. Exclusion criteria are high risk pregnancy based on protocol of integrated health mother's care, having experiences in meditation and yoga, psychological and emotional and physical illness, consumption of drug, elective c/s.

Intervention groups

The intervention group will receive 8 training sessions that are mind-based content, along with routine care in the delivery preparation classes, and the control group will receive the delivery preparation classes.

Main outcome variables

Evaluation of severity of labor pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191208045660N1**

Registration date: **2020-01-15, 1398/10/25**

Registration timing: **prospective**

Last update: **2020-01-15, 1398/10/25**

Update count: **0**

Registration date

2020-01-15, 1398/10/25

Registrant information

Name

zeinab hasanimotlagh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5522 7504

Email address

z.hasanimotlagh72@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mindfulness on labor pain in primiparous women

Public title

The effect of mindfulness on labor pain in primiparous women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

- Primiparous Pregnant Women, from Week 20 to 23

Having at least a third-grade guidance degree Age range 18 to 35 years Single pregnancy

Exclusion criteria:

High-risk pregnancy (based on Integrated Maternal Health Care Booklet) Experience with meditation and yoga Known mental illnesses and drug use Scheduled cesarean birth - Any need for emergency intervention in the mother and fetus in cases such as bleeding, tandem contractions, accelerated labor, fetal distress, premature placental abruption, cesarean section Normal contraindications (placenta previa, pelvic stenosis, no fetal rotation)

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be randomly assigned to the control and intervention groups using a four-block design using a coin throw.

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 qazvin university of medical sciences

Street address

Shahid Bahonar Boulevard - Qazvin University of Medical Sciences

City

qazvin

Province

Qazvin

Postal code

15315-34199

Approval date

2019-11-04, 1398/08/13

Ethics committee reference number

IR.QUMS.REC.1398.178

Health conditions studied

1

Description of health condition studied

Intensity of labor pain in active phase

ICD-10 code

000-099

ICD-10 code description

pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

The severity of labor pain in two groups

Timepoint

after admission the severity of pain at 4, 6, 8, 10 and in second stage and when laceration or episiotomy .

Method of measurement

In the study of the effect of mindfulness on labor pain, how variable measure can be visual analogue scale and McGill questionnaire.

Secondary outcomes

1

Description

Measuring the length of the first, second and third stages of labor

Timepoint

In the study of the effect of mindfulness on labor pain in primiparous women, the timing of measuring the length of the first, second and third stages of labor can be during the active phase of labor and postpartum.

Method of measurement

In studying the effect of mindfulness on labor pain in primiparous women, how the secondary variable measuring the length of the first, second and third stages of labor can be measured in minutes and hours.

2

Description

The severity of episiotomy pain

Timepoint

In the study of the effect of mindfulness on labor pain in primiparous women, time periods of measuring the severity of episiotomy pain may be postpartum and undergoing episiotomy repair.

Method of measurement

In studying the effect of mindfulness on labor pain in primiparous women, how to measure secondary variable of severity of pain can be McGill questionnaire and visual analogue scale .

3

Description

The amount of analgesia used

Timepoint

In the study of the effect of mindfulness on labor pain in primiparous women, time periods are measured to measure the amount of analgesic drug use throughout the labor stages.

Method of measurement

In the study of the effect of mindfulness on labor pain in primiparous women, how to measure the secondary variable of analgesic drug use can be case study and question.

Intervention groups

1

Description

Intervention group: There are 56 pregnant women in this group who will receive routine pregnancy care and childbirth preparation classes + 8 mindfulness training sessions.

Category

Behavior

2

Description

Control group: 56 Pregnant women are in this group who will receive routine pregnancy care and childbirth preparation classes.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Shahid Beheshti Hospital

Full name of responsible person

Mohammad Reza Sharif

Street address

Kashan 5 km Ravand Road, Qotb Ravandi Boulevard, Shahid Dr. Beheshti Hospital Complex

City

Kashan

Province

Isfahan

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87159/81151

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+98 31 5554 0026

Fax

Email

beheshtihospital@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Deputy of research and technology

Street address

Shahid Bahonar Boulevard - Qazvin University of Medical Sciences

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15315-34199

Phone

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Email

info@qums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

zeinabhasanimotlagh

Position

midwifer

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

midwifer

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the data related to the primary and secondary outcomes can be shared.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Researchers working in academic and scientific institutes and research students in this field.

Under which criteria data/document could be used

It is permissible to use results in articles and compare them in new work.

From where data/document is obtainable

E-mail: z.hasanimotlagh72@yahoo.com

z.hasanimotlagh@qums.ac.ir nezalazh@gmail.com

What processes are involved for a request to access data/document

After the applicant's request by email, the necessary reviews will be made and information will be available shortly after approval.

Comments