

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of mindfulness techniques in counseling with and without acupressure on pain and childbirth experience in primiparous women: a randomized controlled clinical trial

Protocol summary

Study aim

The effect of mindfulness technique in counseling with and without acupressure on pain and childbirth experience in primiparous women

Design

This clinical trial on 90 primiparous pregnant mothers who, using RAS (Random Allocation Software) software with a block size of 9 and with a ratio of 1:1:1, were assigned to three groups receiving counseling with mindfulness techniques. Counseling with mindfulness techniques in counseling along with acupressure training and a control group (receiving routine care) will be randomly assigned. In order to hide the allocation, the type of intervention The inside of the matte envelopes are numbered consecutively.

Settings and conduct

The research environment was Taleghani, Al-Zahra ,29 Bahman teaching hospitals. Before the intervention and 24 hours after delivery, midwifery characteristics form, including length of labor and type of childbirth, perceived childbirth pain, experience and support and control in labor will be completed by interview method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: first pregnancy, age 18-45 years, living in Tabriz city, gestational age 32-34 weeks. Exclusion criteria: participation in yoga classes, multiple pregnancy, chronic diseases such as hypertension, cardiovascular diseases, etc., indications for cesarean section and polyhydramnios, IUGR, pregnancy with assisted reproduction methods

Intervention groups

One intervention group will receive mindfulness counseling, the second intervention group will receive mindfulness counseling with acupressure training, and the control group will receive routine care.

Main outcome variables

Perceived childbirth pain, childbirth experience, support

and control during childbirth, length of labor stages, frequency of cesarean section

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171007036615N12**

Registration date: **2024-01-16, 1402/10/26**

Registration timing: **prospective**

Last update: **2024-01-16, 1402/10/26**

Update count: **0**

Registration date

2024-01-16, 1402/10/26

Registrant information

Name

عصمت مهرابی

Name of organization / entity

دانشگاه علوم پزشکی تبریز

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mindfulness techniques in counseling with and without acupressure on pain and childbirth experience in primiparous women: a randomized controlled clinical trial

Public title

The effect of mindfulness techniques in counseling with and without acupressure on pain and childbirth experience in primiparous women: a randomized controlled clinical trial

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Women with first pregnancy Age 18-45 years Living in Tabriz city Gestational age 32-34 weeks at the time of study entry Willingness to give birth in Al-Zahra and Taleghani centers and 29 Bahman Social Security Hospital in Tabriz

Exclusion criteria:

Prior knowledge of yoga Multiple pregnancy Suffering from chronic diseases or induced or aggravated during pregnancy, such as hypertension, cardiovascular diseases, diabetes, preeclampsia, etc. Cesarean indications such as placenta previa, non-cephalic presentations, abnormal fetal heartbeats and... Known indication for caesarean section or hysterectomy Hospitalization after 6 cm dilatation Abnormal pregnancy process such as polyhydramnios, oligohydramnios, intrauterine growth disorder Pregnancy with assisted reproduction methods

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Using Random Allocation Software, RAS, the participants will be assigned to three groups receiving mindfulness counseling without acupressure, mindfulness counseling with acupressure, and the control group with a block size of 9 and with an allocation ratio of 1:1:1. became. Blocking will be done by a person not involved in data sampling and analysis (responsible for the clinic). In order to hide the allocation, the type of intervention will be written on a sheet of paper and placed inside opaque envelopes numbered consecutively. These envelopes will be opened in the presence of the mother and the type of

group will be informed to the mother.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the study, this study is single blind. In this way, the person analyzing the data will not be aware of the type of intervention groups.

Placebo

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University, University Koi, Vice-Chancellor of Technology Research, Tabriz University of Medical Sciences

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Tabriz

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East Azarbaijan

Postal code

5138947977

Approval date

2024-01-01, 1402/10/11

Ethics committee reference number

IR.TBZMED.REC.1402.741

Health conditions studied**1****Description of health condition studied**

pain of child birth

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Understanding labor pain score

Timepoint

24 hours after delivery

Method of measurement

Childbirth Pain Perception Questionnaire

2

Description

Birth experience score

Timepoint

24 hours after delivery

Method of measurement

Denker childbirth experience questionnaire

Secondary outcomes

1

Description

The score of support and control in birth

Timepoint

24 hours after delivery

Method of measurement

Support and Control in birth questionnaire

2

Description

Length of labor stages score

Timepoint

24 hours after delivery

Method of measurement

Viewing/checking partograph and midwifery profile section

3

Description

Cesarean frequency score

Timepoint

24 hours after delivery

Method of measurement

View/check the midwifery profile section

Intervention groups

1

Description

The first intervention group: pregnant mothers who are in this group will receive 8 counseling sessions with mindfulness content, including two sessions per week in person (in groups of 4-6 people), each session lasting 45 minutes. The second intervention group: They will receive 8 counseling sessions with mindfulness content, including two sessions per week in person (in groups of 4-6 people), each session lasting 45 minutes. For the intervention group receiving mindfulness with acupuncture stimulation of pressure points (KD1 (Kidney 1), SPECIAL HAND-COMB TECHNIQUE) will be taught. In case the mother is unable to participate in the counseling sessions for 1-2 sessions, further training will be provided with telephone and virtual follow-ups. Finally, after the delivery bed and stabilization of the situation in the delivery room, for each of the women in the mindfulness group, mindfulness techniques training Awareness will be reminded. The control group will receive routine pregnancy care training.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital Tabriz

Full name of responsible person

Maryam Vaez

Street address

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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3

Recruitment center

Name of recruitment center

29 Bahman Hospital

Full name of responsible person

Lida Heidari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Esmat Mehrabi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

"There is no further information"

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available