Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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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mehrabie@tbzmed.ac.ir

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
City
Tabriz
Province
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 acupressure 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
Al-Zahra Medical Education Center (S),Baghshamal Crossroads, South Army Street,
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2

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
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3

Recruitment center
Name of recruitment center
29 Bahman Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Midwifery

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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