Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of mindfulness-based counseling on childbirth experience and support and control among nullipar women: a randomised controlled clinical trial

Protocol summary

Study aim

The effect of mindfulness-based counseling on experience, support and control of childbirth

Design

A clinical trial study on 64 primiparous mothers (32 in the intervention group and 32 in the control group) using RAS (Random Allocation Software) software with a size of four or six blocks and an allocation ratio of 1 : 1 will be divided into two groups receiving counseling and control group.

Settings and conduct

The research environment will be Taleghani and Al-Zahra teaching hospitals. Before the intervention and 24 hours after delivery, the participants will complete the questionnaires of delivery experience, support and control, and pain delivery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: first delivery؛live fetus؛ cephalic singleton؛ tendency to give birth in Al-Zahra and Taleghani hospitals؛lack of mental disability and deafness. Inclusion criteria: history of pre-pregnancy mental disorders according to the patient؛ abnormal volume of amniotic fluid؛ nst non-reactıve؛Fetal abnormalities؛ Have any surgery on the uterus؛ Have a high-risk pregnancy؛ Pregnancy with the help of assisted reproductive techniques؛

Intervention groups

Intervention group: Receiving a counseling program with a mindfulness approach will be done in 8 45-minute group sessions. Control group: Routine care training in pregnancy will be held as a session every week online and in person.

Main outcome variables

Childbirth experience score, support and control score, labor pain score, labor fear score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171007036615N9**
Registration date: **2022-03-16, 1400/12/25**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-16, 1400/12/25**
Update count: **0**

Registration date

2022-03-16, 1400/12/25

Registrant information

Name

عصمت مهرابی

Name of organization / entity

دانشگاه علوم پزشکی تبریز

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 0649

Email address

mehrabie@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-07, 1400/11/18

Expected recruitment end date

2022-04-07, 1401/01/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of mindfulness-based counseling on childbirth experience and support and control among nullipar women: a randomised controlled clinical trial

Public title
The effect of mindfulness-based counseling on nulliparous women

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
The first delivery Live cephalic single fetus Tendency to give birth in Al-Zahra and Taleghani hospitals Lack of mental disability and deafness

Exclusion criteria:
1. History of pre-pregnancy mental disorders according to the patient3. 4. 5. 6. 7. 8. 9. 10. Abnormal volume of amniotic fluid NST non-reactive Fetal malformations Have any surgery on the uterus Having high-risk pregnancies such as hypertension, diabetes, placenta previa, cardiovascular disease and other chronic diseases, bleeding in the third trimester, placental abruption, placenta previa, fetal growth disorder Pregnancy with the help of assisted reproductive techniques The desire to receive other pharmacological and non-pharmacological analgesics Unplanned pregnancy Any contraindications for vaginal delivery, including pelvic series mismatch

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants using the RAS(Random Allocation Software)with the size of 4 and 6 blocks and quotas based on the type of labor pain onset (spontaneous or induction) and with a ratio of 1: 1 to the two groups receiving mindfulness counseling and allocation control group Will be given. Blocking was performed by a person not involved in sampling and data analysis. For concealment, the intervention type assignment will be written on a piece of paper and placed in matte envelopes and numbered in a row. These envelopes will be opened in the presence of the mother and by a person not involved in sampling (in charge of the hospital clinic) and the type of group will be informed to the mother.

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 Tabriz University of Medical Sciences

Street address
Tabriz college of Nursing and Midwifery, South Shariati St., Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5138947977

Approval date
2022-02-06, 1400/11/17

Ethics committee reference number
IR.TBZMED.REC.1400.1121

Health conditions studied

1

Description of health condition studied
childbirth experience and support and control

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Childbirth experience score

Timepoint
24 hours after delivery

Method of measurement
Denker Childbirth Experience Questionnaire

2

Description
Support and control score

Timepoint
Before intervention and 24 hours after delivery

Method of measurement
Support and control questionnaire

Secondary outcomes

1

Description
Pain perception score
Timepoint
Dilatation at 6 cm and 24 hours after delivery
Method of measurement
Childbirth pain questionnaire Visual Analog Scale

2

Description
Fear of childbirth score
Timepoint
Dilatation at 6 cm and 24 hours after delivery
Method of measurement
Fear of childbirth in the labor stage will be using the WDE-Q (A) questionnaire and in the postpartum stage with the WDE-Q (B) fear of childbirth questionnaire.

Intervention groups

1

Description
Intervention group: Pregnant mothers who are in the mindfulness group, for 8 sessions of counseling program with the content of mindfulness as walking: walking slowly and intentionally and paying attention to movements, weight changes and balance and sensations in the legs that are related to walking. The process of eating: continues by feeling the raisins in the mouth, biting them, paying attention to the taste and texture, and the sensations and movements of the mouth and throat while chewing and swallowing the raisins. Awareness is done. Body scan: When lying on your back for 40 minutes, your attention is directed to different parts of your body (from toes to head) and you pay attention to the emotions in every part of your body with openness and curiosity.Sitting meditation: In a sitting position, the person is asked to pay attention to the feelings and movements of breathing. The person is instructed to pay attention to bodily feelings without judgment and acceptance. Yoga: Slow and gradual yoga Hatha Consciously nurtures the body when moving, stretching or maintaining a posture. Enters the body slowly and deeply into a dome-shaped body and abdomen, and then exhale very slowly without any pressure or contraction. It will be a minute.The assignments requested from the mothers in cyberspace will be reviewed by the researcher and the mother will be given feedback. Finally, after hospitalization and stabilization in the delivery room for each of the women in the mindfulness group, she will be reminded of the trainings of mindfulness techniques and in order to perform the steps of mindfulness correctly during labor and dilation of six centimeters (Active phase of labor) will guide.
Category
Behavior

2

Description
Control group:. For the control group of routine care training (Trainings based on the educational content of physiological delivery, including nutritional, health, exercise and information's about physiological delivery and pain relief delivery methods) in pregnancy will be held as a session every week online and in person.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani
Full name of responsible person
Bahareh Sharegi
Street address
Taleghani Hospital،Railway Square، Tabriz، East Azerbaijan
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2

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Bahareh Sharegi
Street address
Al-Zahra Educational and Medical Center, Baghshamal Intersection, South Army Street ،Tabriz،East Azarbaijan
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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr Parviz Shahabi

Street address
Vice Chancellor for Technology Research, Tabriz University of Medical Sciences

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permaosku2013@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

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
Ph.D in reproductive health

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

Contact

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Full name of responsible person
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Position
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Reproductive Health

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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