Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Effect of foot reflexology on labor pain intensity and childbirth experience in primiparous women: a randomized controlled clinical trial

Protocol summary

Study aim
To determine the effect of foot reflexology on labor pain intensity and childbirth experience in primiparous women

Design
Clinical trial, with control group, with parallel groups, double blind, randomized

Settings and conduct
This randomized controlled clinical trial will be conducted in Al-Zahra and Taleghani hospitals of Tabriz. Participants will be divided into three groups by randomized blocking method and an assignment ratio of 1:1:1. The intervention group 1 will receive 30-minute reflexology twice at the effective pain point. The intervention group 2 will receive a 30-minute massage at the pain point and a 30-minute massage at the heel for each foot, and the control group will receive 30-minute massage at the heel twice for better blindness.

Participants/Inclusion and exclusion criteria
The participants will be nulliparous women with 38-42 weeks gestational age.

Intervention groups
The Intervention group will be intervention 1 (twice massage for 30 minutes at the effective point of pain for each foot), Intervention 2 (one 30 minutes massages at the effective point of pain, and one 30 minute massage on the heel for each foot) and control group (twice 30 minutes massage on the heels for each foot).

Main outcome variables
The main outcomes will be pain severity mean during labor and childbirth experience score.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120718010324N53**
Registration date: **2020-01-02, 1398/10/12**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-02, 1398/10/12**
Update count: **0**

Registration date
2020-01-02, 1398/10/12

Registrant information

Name
Mojgan Mirghafourvand

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 41 1479 6969

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-30, 1398/10/09

Expected recruitment end date
2020-06-19, 1399/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of foot reflexology on labor pain intensity and childbirth experience in primiparous women: a randomized controlled clinical trial

Public title
The effect of foot reflexology on pain intensity and child

birth experience in primiparous women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

primiparous women Gestational age 38-42 weeks Singleton pregnancy Cephalic presentation of the fetus Intact amniotic sac Having no history of infertility Not having any physical or mental illness No drug addiction Low risk pregnancy (no third trimester bleeding, placental abruption, placenta previa, fetal developmental disorder, etc.) No indication of cesarean section No infection or obstruction at the massage site No taking of drugs for pain relief up to 4 hours before intervention

Exclusion criteria:

Attending in reflexology classes History of chronic systemic diseases including heart and pulmonary Diseases according to the patient statement. Any skin disorders and bone fractures at the massage site Receiving of analgesic medication (receiving epidural anesthesia and intravenous remifentanil infusion) Receiving other non-pharmacological analgesics Accelerated labor

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be assigned into three groups by block randomization method with block sizes of 3 and 6 and allocation ratio of 1:1:1 including intervention 1 (twice massage for 30-minutes at the effective point of pain for each foot), Intervention 2 (one 30-minutes massages at the effective point of pain, and one 30-minute massage on the heel for each foot), and control (twice 30-minutes massage on the heels for each foot). The allocation sequence will be determined by the person who is'n involved in the sampling and data collection.

Blinding (investigator's opinion)

Double blinded

Blinding description

The present study is a single-blind randomized controlled clinical trial (participant and data analyst will be unaware of the type of intervention received). Participants will be blinded by foot massage in all three group (at the effective point of pain or the heel of foot). Data analyses will be conducted by a person who will be unaware of the type of intervention received by groups and the groups will be categorized with letters of A, B and C.

Placebo

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

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan

City

Tabriz

Province

East Azarbaijan

Postal code

00984113357311

Approval date

2019-11-24, 1398/09/03

Ethics committee reference number

IR.TBZMED.REC.1398.907

Health conditions studied

1

Description of health condition studied

Delivery

ICD-10 code

O80.0

ICD-10 code description

Spontaneous vertex delivery

Primary outcomes

1

Description

Pain severity during labor

Timepoint

Before the intervention and every hour during the active phase of labor

Method of measurement

Visual analog scale

2

Description

Childbirth experience

Timepoint

12 to 24 hours after delivery

Method of measurement

Labor Agency Scale

Secondary outcomes

1

Description
Duration of active phase of delivery
Timepoint
From dilatation 4 cm until full dilatation of cervix
Method of measurement
Partograph chart (minute)

2

Description
Duration of second stage of delivery
Timepoint
From full dilatation of cervix until birth of newborn
Method of measurement
Partograph chart (minute)

3

Description
Duration of Third stage of delivery
Timepoint
From birth of newborn until complete expulsion of placenta
Method of measurement
Partograph chart (minute)

Intervention groups

1

Description
The intervention group 1 will receive 30-minute reflexology twice at the effective pain point.
Category
Treatment - Other

2

Description
The intervention group 2 will receive a 30-minute massage at the pain point and a 30-minute massage at the heel for each foot.
Category
Treatment - Other

3

Description
The control group will receive 30-minute massage twice at the heel for each foot.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Educational and Treatment Center, Tabriz
Full name of responsible person
Masoumeh Ghameei Moghadam
Street address
Alzahra Educational and Treatment Center, South Artesh street, Tabriz
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2

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

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Samiei
Street address
Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz
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mirghafourvandm@tbzmed.ac.ir

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

Masoumeh Jameei Moghadam

Position

MSc student of Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Faculty of Nursing & Midwifery, South Shariati Street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Mojgan Mirghafourvand

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

Midwifery

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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

Participants data is confidential

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

The results of clinical study will be published as article.

When the data will become available and for how long

Immediately after publishing the results.

To whom data/document is available

All researchers

Under which criteria data/document could be used

Scientific using with citation to article

From where data/document is obtainable

Email: mirghafourvandm@tbzmed.ac.ir

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

Up to one week after communication by email

Comments