

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

Registration timing: **registered_while_recruiting**

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**

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)

Phone

+98 41 1479 6969

Email address

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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 remifentanyl 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,
Golgash 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

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

Taleghani Educational and Treatment Center, Tabriz

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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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mojgan Mirghafourvand

Position

Associate Professor

Latest degree

Ph.D.

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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Position

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Latest degree

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Other areas of specialty/work

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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