

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of the effect of two methods of distraction thinking and Therapeutic touch in reducing labor pain in nulliparous women

Protocol summary

Study aim

Determining the effect of distraction thinking and Therapeutic touch in reducing labor pain in nulliparous women

Design

The clinical trial has two intervention groups and one control group with parallel groups Randomized by random block method in 12 blocks of 6 from the table of random numbers on 72 people

Settings and conduct

The research environment will be the birth preparation classes of Khalkhal city. Eligible people will be randomly assigned to one of the three groups of touch therapy, thought distraction technique, and control. The intervention group will be trained with touch therapy technique in one session and the intervention group will be trained with distraction technique (watching a movie), based on the existing protocol and in 4 sessions. The control group will also receive routine care. Then the mothers will contact the researcher upon entering the active phase of labor and the researcher will conduct the intervention in the study groups.

Participants/Inclusion and exclusion criteria

nulliparous women in the age range of 15-35 years
Pregnancy without maternal and fetal complications
Gestational age 28-32 weeks Obtaining an average pain score from the visual pain scale

Intervention groups

The intervention group with therapeutic touch technique (the researcher will touch the mother's hands for 15 minutes with rhythmic and calm movements, without any pressure, at the beginning of uterine contractions in the active phase of labor, which is from dilation of 6 cm to entering the second stage of labor) They will receive a training session. The intervention group will participate in four sessions with distraction technique (watching a movie) which will be held weekly based on the existing protocol. The control group will receive routine care and will receive training package at the end.

Main outcome variables

labor pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151211025477N6**

Registration date: **2022-12-28, 1401/10/07**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-28, 1401/10/07**

Update count: **0**

Registration date

2022-12-28, 1401/10/07

Registrant information

Name

Elahe Ahmadnia

Name of organization / entity

Social determinants of health center

Country

Iran (Islamic Republic of)

Phone

+98 24 3344 9192

Email address

ahmad@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-21, 1401/08/30

Expected recruitment end date

2023-03-19, 1401/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effect of two methods of distraction thinking and Therapeutic touch in reducing labor pain in nulliparous women

Public title
Comparison of the effect of two methods of distraction thinking and Therapeutic touch in reducing labor pain in nulliparous women

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
nulliparous women in the age range of 15-35 years
Pregnancy without maternal and fetal complications
Gestational age 28-32 weeks
Willingness to participate in research
Having a phone and contact number
Not having hearing and vision problems
Obtaining an average pain score from the visual pain scale
Willingness to have a natural birth at the Imam Khomeini (RA) Khalkhal Educational and Medical Hospital
Has at least middle school education
Exclusion criteria:
Indications for cesarean include: abnormal presentation of the fetus, pelvic stenosis, large fetus
Occurrence of adverse fetal outcomes
Inability to understand the scale of the pain ruler
Analgesic injection

Age
From **15 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling in this research will be done in an easy and accessible way and based on the entry criteria. Allocation of participants to 3 groups will be done by random block method in 12 blocks of 6. In such a way, two people from the first intervention group (AA), two people from the second intervention group (BB) and two people from the control group will be present in each block. Then the different states of placing these people in the blocks will be predicted and a number will be assigned to each state, then the required number of random numbers will be extracted from the table of random numbers until the study sample size is reached, and based on them, the arrangement of the participants in Groups will be determined. Matte envelopes will be prepared by the thesis advisor before sampling and will be numbered according to the sample volume. Within each envelope, the allocation of a person to one of the study groups will be determined based on the random allocation of the

block. Then, at the time of entering the study, the envelope will be selected based on the participant's code and opened in their presence, and the selected person will be placed in one of the three groups.

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

The Ethics Committee of Zanzan University of Medical Sciences

Street address

Zanzan University of Medical Sciences, Azadi Blvd, Zanzan

City

Zanzan

Province

Zanzan

Postal code

4515613191

Approval date

2022-10-28, 1401/08/06

Ethics committee reference number

IR.ZUMS.REC.1401.207

Health conditions studied

1

Description of health condition studied

Delivery

ICD-10 code

O80.9

ICD-10 code description

Single spontaneous delivery, unspecified

Primary outcomes

1

Description

Labor pain score

Timepoint

Before and after the intervention

Method of measurement

Visual analog pain scale (WONG-BAKER Pain Scale) to prevent misappropriation by the colleague present in the block who is unaware of the type and process of the

intervention and the pain ruler (VAS = Visual Analogue Scale) by the mother herself once every hour in the phase Active labor (from the entry of the participating women to dilation of 6 cm until the entry into the second stage of labor) will be measured

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For. Therapeutic touch technique, a 45-minute counseling session will be held according to the protocol during pregnancy. Then, in the active phase of labor (dilation of 6 cm until entering the second stage of labor), the researcher will touch the hands of the people of this group for 15 minutes with rhythmic and calm movements (without any pressure) at the beginning of the mother's pains.

Category

Behavior

2

Description

Intervention group: For the Distraction technique (watching the movie), four 45-minute counseling sessions will be held one week apart based on the existing protocol during pregnancy. Then the researcher will play 15-minute clips (with different pre-prepared contents) according to the mother's interests in the active phase of labor (6 cm dilation until entering the second stage of labor) at the beginning of the mother's pain.

Category

Behavior

3

Description

Control group: Routine care

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital (RA) - delivery room

Full name of responsible person

Leila Mikaelzadeh

Street address

Imam Rah Khalkhal educational and treatment center, Basij Square

City

Khalkhal

Province

Ardabil

Postal code

5681966675

Phone

+98 45 3242 7438

Email

m.dar@khalums.ac.ir

Web page address

<https://khalums.ac.ir/dar/fa>

2

Recruitment center

Name of recruitment center

Childbirth preparation class

Full name of responsible person

Ashraf Najafzadeh

Street address

Old Hospital, Shahid Mozafar Azizi Street

City

Khalkhal

Province

Ardabil

Postal code

5681761351

Phone

+98 45 3242 6802

Email

info@khalums.ac.ir

Web page address

<https://khalums.ac.ir/fa>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Alireza Shoghli

Street address

Chancellor for Research and Technology of Zanjan University of Medical Sciences, First floor, Northside Boulevard Azadi

City

Zanjan

Province

Zanjan

Postal code

4515613191

Phone

+98 24 3314 8300

Fax

+98 24 3314 8300

Email

shoghli@zums.ac.ir

Grant name

Thesis

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Zanjan University of Medical Sciences

Proportion provided by this source

10

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**

Zanjan University of Medical Sciences

Full name of responsible person

Zahra Bakhtiari

Position

Msc student of counseling in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Omran Posti St, Jhanbazan St

City

Khalkhal

Province

Ardabil

Postal code

5681863435

Phone

+98 45 3241 1099

Email

mhy.bakhtairi@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Dr Elahe Ahmadnia

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Zanjan University of Medical Sciences, Gavazang Road

City

Zanjan

Province

Zanjan

Postal code

4515613191

Phone

+98 24 3314 8300

Email

Ahmad@zums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Zahra Bakhtiari

Position

Msc student of counseling in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Omran Posti St, Jhanbazan St

City

Kalkhal

Province

Ardabil

Postal code

5681863435

Phone

+98 45 3241 1099

Email

mhy.bakhtiari@gmail.com

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

Yes - There is 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

Title and more details about the data/document

Only part of the information, such as information on the main outcome or the like, can be shared.

When the data will become available and for how long

One year after the publication of the results as an article

To whom data/document is available

Researchers

Under which criteria data/document could be used

In order to complete the studies

From where data/document is obtainable

Researcher and adviser

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

6 months

Comments