

# 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

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##### 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

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##### Province

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+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

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Omran Posti St, Jhanbazan St

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**Province**

Ardabil

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5681863435

**Phone**

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**Email**

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

Zanjan University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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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

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**City**

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**Province**

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**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**