# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## A comparative study of the effect of squats and butterfly movements on pain intensity and duration of labor in primiparous women.

## Protocol summary

**Study aim**
Comparative determination of the effect of squat and butterfly exercise on the intensity of pain and the length of labor stages in primiparous women

**Design**
This study is a randomized, single-center, three-group, parallel-group, open-label clinical trial that will be conducted on 84 primiparous women (28 women per group). Participant allocation will be done using a block randomization method and a sequence generated by Microsoft Excel software with an allocation ratio of 1:1:1.

**Settings and conduct**
Primiparous women who present to the delivery room of Iran Hospital, Iranshahr with labor pain and 3-4 cm dilation and meet the inclusion criteria will then be assigned to three groups of squats, butterfly movements, and control using a block random assignment method.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Primiparous women with a gestational age of 37 to 42 weeks and singletons who have full consent to participate in the study and are members of the Vertex Fetal Display. Exclusion criteria: Mother's withdrawal from participation in the study at any stage of the study, any factor that causes emergency cesarean section, use of vacuum, receiving any type of analgesia during the study, in the event of any abnormal changes in the fetal ECG or fetal distress during the study

**Intervention groups**
Three parallel groups will be conducted, including the Squat group, the Butterfly group, and the control group.

**Main outcome variables**
Reducing the intensity of pain and the length of labor

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20260619069866N1**
Registration date: **2026-06-30, 1405/04/09**
Registration timing: **prospective**

Last update: **2026-06-30, 1405/04/09**
Update count: **0**

**Registration date**
2026-06-30, 1405/04/09

**Registrant information**

**Name**
Mahtab Karimi

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2026-07-23, 1405/05/01

**Expected recruitment end date**
2026-09-23, 1405/07/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
A comparative study of the effect of squats and butterfly movements on pain intensity and duration of labor in primiparous women.

**Public title**
A comparative study of the effect of squats and butterfly

movements on pain intensity and duration of labor stages.

**Purpose**

Diagnostic

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Primiparous women with gestational age 37 to 42 weeks A singleton who has full consent to participate in the study. Be a member of the Vertex embryo show The fetal position is occiput anterior. The mother is in the active phase and is 3 to 4 centimeters dilated.

**Exclusion criteria:**

Preterm birth Fetal distress Premature rupture of the water bag for more than 12 hours Severe gestational hypertension Preeclampsia and eclampsia severe anemia Abnormal presentation twins Receiving epidural or gastox anesthesia Suspected pelvic stenosis High maternal body mass index (more than 30) Deculman and Pervia History of previous caesarean section Posterior occiput position Suspected fetal macrosomia Maternal joint and skeletal problems Doubt to FGR Congenital fetal anomaly Known chronic disease in the mother (heart, kidney, diabetes, etc.). Attend childbirth preparation classes and yoga during pregnancy Mother's withdrawal from participation in the study at any stage of the research Any factor that causes an emergency cesarean section Use of vacuum Receiving any type of pain relief during the study If any abnormal changes occur in the fetal ECG or fetal distress occurs during the study

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **84**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Sampling will be done by convenience sampling. In this way, primiparous women referring to the maternity ward of Iran Hospital, Iranshahr, who meet the inclusion criteria, were included in the study after receiving the necessary explanations and signing the informed consent form. After entering the study, participants will be assigned to one of three groups (squat exercise), (butterfly movement), (control group) using a block randomization method with an allocation ratio of 1:1:1. The random sequence of blocks is prepared before the study begins by a person who is not involved in conducting the research and collecting the data, using random number generation software. The allocation sequence is placed in opaque, sealed, opaque, numbered, and consecutive envelopes. After meeting the entry requirements and obtaining informed consent, the researcher opens the envelope corresponding to the same number and allocates the participant to one of the three study groups based on the group designated in the envelope. To prevent bias, the randomization sequence will be kept confidential until each participant is allocated, and it will not be possible to predict the assigned group. Given the nature of the intervention, blinding of participants and the researcher is not possible; however, statistical analysis of the data will be performed by someone who is unaware of the group allocation.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

This study is the first clinical trial in the study area to directly compare the effects of two non-pharmacological interventions, including squats and butterfly pose (Baddha konasana), on pain intensity and duration of labor in primiparous women. Both phases of the intervention are performed during the active phase of labor and in the real delivery room environment. Also, the existence of three parallel groups, including the squat group, the butterfly group, and the control group, allows for a precise comparison of the effectiveness of these two interventions with usual care. The results of this study can provide practical evidence for the use of simple, low-cost, safe, and feasible interventions in the delivery room.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of iranshahr university of medical sciences

**Street address**

Moalem Boulevard

**City**

Iranshahr

**Province**

Sistan-va-Balouchestan

**Postal code**

9916643535

**Approval date**

2026-01-31, 1404/11/11

**Ethics committee reference number**

IR.IRSHUMS.REC.1404.039

## Health conditions studied

### 1

**Description of health condition studied**

Child Birth

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Gestational age
**Timepoint**
Before intervention
**Method of measurement**
Based on the week of pregnancy recorded in the pregnancy record

### 2

**Description**
Economic situation
**Timepoint**
Before intervention
**Method of measurement**
Based on participant self-declaration and demographic information questionnaire

### 3

**Description**
The length of the first stage of labor
**Timepoint**
During the intervention
**Method of measurement**
From 3 cm to 10 cm dilation

### 4

**Description**
Length of the second stage of labor
**Timepoint**
During the intervention
**Method of measurement**
From 10 cm dilation to delivery of the fetus

### 5

**Description**
Desire to get pregnant
**Timepoint**
Before intervention
**Method of measurement**
Based on participant self-declaration and demographic information questionnaire

### 6

**Description**
Wife's job
**Timepoint**
Before intervention
**Method of measurement**
Based on participant self-declaration and demographic information questionnaire

### 7

**Description**
Spouse's level of education
**Timepoint**
Before intervention
**Method of measurement**
Based on participant self-declaration and demographic information questionnaire

### 8

**Description**
Mother's job
**Timepoint**
Before intervention
**Method of measurement**
Based on participant self-declaration and demographic information questionnaire

### 9

**Description**
Mother's level of education
**Timepoint**
Before intervention
**Method of measurement**
Based on participant self-declaration and demographic information questionnaire

### 10

**Description**
Severity of labor pain
**Timepoint**
After the intervention
**Method of measurement**
Measurement with a visual pain scale from zero to 10 at specific time intervals

### 11

**Description**
Mother's height
**Timepoint**
Before intervention
**Method of measurement**
According to the measurement carried out

### 12

**Description**
Mother's weight
**Timepoint**
Before intervention
**Method of measurement**
According to the measurement carried out

### 13

**Description**
Squat movements
**Timepoint**
During the intervention

**Method of measurement**
Performing squats according to the prescribed protocol

**14**

**Description**
Butterfly movements
**Timepoint**
During the intervention
**Method of measurement**
Performing the butterfly movement according to the established protocol

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: First intervention group: Squat movements are performed 5 times, each time for 3 to 5 deep breaths, held in the squat position for 30 seconds, and performed for 3 sets of 5, 30 seconds each, in 45 minutes. In the next 15 minutes, we will perform a vaginal examination and perform a triage, and a partograph form will be drawn. This process will continue until delivery.
**Category**
Diagnosis

**2**

**Description**
Intervention group: Second intervention group: The butterfly movement group also performs butterfly movements for 2 minutes under the supervision of a midwife, and for 3 sets of 2 minutes at 15-minute intervals, the butterfly movement is performed for 45 minutes, and for the next 15 minutes, we will perform a vaginal examination and perform a tracheotomy, and a partograph form will be drawn. This process will continue until delivery.
**Category**
Diagnosis

**3**

**Description**
Control group: The third group, which is the control group, receives routine hospital care.To eliminate the placebo effect, non-specific movement or soft touch will be used for the control group.
**Category**
Diagnosis

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Iran Hospital, Iranshahr
**Full name of responsible person**
Mahtab Karimi
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Moalem Boulevard
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Iranshahr University of Medical Sciences
**Full name of responsible person**
Masoud Kikha
**Street address**
Moalem Boulevar
**City**
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**Province**
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+98 54 3721 3892
**Email**
info@irshums.ac.ir
**Web page address**
http://irshums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Iranshahr 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**

Iranshahr University of Medical Sciences

**Full name of responsible person**

Mahtab karimi

**Position**

Master's degree student in midwifery

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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## Person responsible for scientific inquiries

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**Full name of responsible person**

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**Position**

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## Person responsible for updating data

**Contact**

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

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

**When the data will become available and for how long**

Access period starts 6 months after results are published.

**To whom data/document is available**

It will only be available to researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

To write an article and if you have an academic email

**From where data/document is obtainable**

To receive the required documents or data, applicants should send a message to the following email: mahtabkarimi7557@gmail.com Contact number: 09906449438

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

Data will be sent within a week after reading the email.

**Comments**