

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Effect of using breathing techniques versus not using on anxiety, duration and severity of labor pain in primiparous women: a randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of using breathing techniques versus not using on anxiety, duration and severity of labor pain in primiparous women

##### Design

This is a randomized clinical trial, in which 140 eligible primiparous women will be randomly assigned to the intervention and control groups

##### Settings and conduct

The primiparous women who will refer to Health Centers of Tuyserkan City during the study period will be enrolled in the trial

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age of 18 to 35 years; gestational age of 30 to 32 weeks; singleton; literate; mild to moderate anxiety score. Exclusion criteria: Chronic disease such as hypertension, diabetes, asthma, cardiovascular diseases, and respiratory diseases; pregnancy complications such as gestational diabetes, preeclampsia, bleeding, placenta previa, signs of preterm labor; oligohydramnios and polyhydramnios; psychological disorders and stress; psychological disorders and stress; macrosomia.

##### Intervention groups

Intervention group: routine education and care before childbirth plus educationa session of how to use breathing techniques one hour weekly for 4 weeks.  
Control group: just routine education and care before childbirth.

##### Main outcome variables

Anxiety; the severity of labor pain; the duration of labor pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N240**

Registration date: **2018-10-07, 1397/07/15**

Registration timing: **prospective**

Last update: **2018-10-07, 1397/07/15**

Update count: **0**

##### Registration date

2018-10-07, 1397/07/15

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-23, 1397/08/01

##### Expected recruitment end date

2019-04-21, 1398/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of using breathing techniques versus not using on

anxiety, duration and severity of labor pain in primiparous women: a randomized clinical trial

#### Public title

Effect of using breathing techniques versus not using on anxiety, duration and severity of labor pain in primiparous women: a randomized clinical trial

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age range: 18 to 35 years old Gestational age: 30 to 32 weeks Singleton pregnancy Being literate Mild to moderate anxiety score

##### Exclusion criteria:

Chronic disease such as hypertension, diabetes, asthma, cardiovascular diseases, and respiratory diseases Pregnancy complications such as gestational diabetes, preeclampsia, bleeding, Placenta Previa, signs of preterm labor oligohydramnios and polyhydramnios; psychological disorders and stress Psychological disorders and stress Macrosomia

#### Age

From **18 years** old to **35 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **140**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization

#### 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

Ethics Committee of Hamadan University of Medical Sciences

##### Street address

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

#### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838695

#### Approval date

2018-09-22, 1397/06/31

#### Ethics committee reference number

IR.UMSHA.REC.1397.429

## Health conditions studied

### 1

#### Description of health condition studied

Anxiety

#### ICD-10 code

F06.4

#### ICD-10 code description

Anxiety disorder due to known physiological condition

### 2

#### Description of health condition studied

labor pain

#### ICD-10 code

R10.2

#### ICD-10 code description

Pelvic and perineal pain

## Primary outcomes

### 1

#### Description

Assessing anxiety

#### Timepoint

During labor

#### Method of measurement

By using Spielberger questionnaire

### 2

#### Description

Assessing the severity of labor pain

#### Timepoint

During labor

#### Method of measurement

By using Visual Analog Scale (VAS)

### 3

#### Description

Assessing the duration of labor pain

#### Timepoint

During labor

#### Method of measurement

By taking history

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Routine education and care before childbirth plus educationa session of how to use breathing techniques one hour weekly for 4 weeks

#### Category

Prevention

### 2

#### Description

Control group: Just routine education and care before childbirth

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Health Centers of Tuyserkan City

##### Full name of responsible person

Faezeh Fazli

##### Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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6517838695

##### Phone

+98 81 3838 0572

##### Email

faezehbehnam7@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr Saeid Bashirian

##### Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

##### Full name of responsible person

Faezeh Fazli

##### Position

Midwifery Student

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery

##### Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.  
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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Full name of responsible person

Dr. Parisa Parsa

##### Position

Community Health Specialist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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**Email**

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## 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**

Undecided - It is not yet known if there will be 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