

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Effect of Guided Visualization on Anxiety and Severity of Labor Pain in Primipara Women

#### Protocol summary

##### Study aim

Determine the effect of guided visualization on anxiety and severity of labor pain in primipara women

##### Design

A randomized clinical trial with two groups (test and control) with parallel groups

##### Settings and conduct

This study was a randomized clinical trial and women were randomly divided into two groups of control and test. The sample size was 25 in each group and the location of the research was 22 Bahman hospital in Gonabad. For women in the experimental group, in addition to routine care at the onset of the active phase of labor (dilatation 3-4), the guided visualization, for 18 minutes through Headphones were broadcast, which included visual or beautiful scenery, only routine care was provided in the control group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The age range is 18-35years first Pregnancy Women before active phase of labor (dilatation less than 3-4 cm) Gestational age 37-42weeks Single throat embryo Embryonic Cephalic Condition Conscious Consent to Participate in the Study No-entrance criteria: Pregnancy Infection with polyhydraminosis and oligohydroaminosis known by ultrasound Known for mental illness Known for chronic diseases

##### Intervention groups

For women in the test group, in addition to routine care at the onset of the active phase of labor (dilatation 4-3), the guided visualization was broadcast for 18 minutes via headphones, which included the visualization of beautiful or pleasant scenery, in the control group only care Routine.

##### Main outcome variables

Anxiety and pain intensity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180221038821N2**

Registration date: **2019-03-10, 1397/12/19**

Registration timing: **retrospective**

Last update: **2019-03-10, 1397/12/19**

Update count: **0**

##### Registration date

2019-03-10, 1397/12/19

##### Registrant information

##### Name

Iman Ghorbany Moghaddam

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 5722 0576

##### Email address

ghorbani.i@gmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2015-02-20, 1393/12/01

##### Expected recruitment end date

2015-06-22, 1394/04/01

##### Actual recruitment start date

2017-02-19, 1395/12/01

##### Actual recruitment end date

2017-06-15, 1396/03/25

##### Trial completion date

2017-07-23, 1396/05/01

##### Scientific title

Effect of Guided Visualization on Anxiety and Severity of Labor Pain in Primipara Women

#### Public title

Effect of Guided Visualization on Anxiety and Severity of Labor Pain in Primipara Women

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

The age range is 18-35 years first Pregnancy Women before active phase of labor (dilatation less than 3-4 cm) Gestational age 37-42weeks Single throat embryo Embryonic Cephalic Condition Conscious Consent to Participate in the Study

##### Exclusion criteria:

Pregnancy Blood Pressure Infection with polyhydraminosis and oligohydroaminosis known by ultrasound Known for mental illness Known for chronic diseases

#### 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: **50**

Actual sample size reached: **50**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

At first, the patients were selected by objective sampling method and applying the entry criteria and then divided into control and test groups by simple random method (throwing coins).

#### 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

Ethical Committee of Gonabad University of Medical Sciences

###### Street address

Gonabad University of Medical Sciences, Asian Road Rim

#### City

Gonabad

#### Province

Razavi Khorasan

#### Postal code

96916-47161

#### Approval date

2015-02-20, 1393/12/01

#### Ethics committee reference number

GMU.AC.1393.126

### Health conditions studied

#### 1

##### Description of health condition studied

Pregnancy

##### ICD-10 code

Z34.0

##### ICD-10 code description

Encounter for supervision of normal first pregnancy

### Primary outcomes

#### 1

##### Description

Intensity of pain

##### Timepoint

Before the intervention, the active phase of labor was started (dilatation more than 3-4 cm) and after intervention the severity of labor pain was measured at dilatation of 6 - 7 and 9- 10.

##### Method of measurement

McGill Painter

#### 2

##### Description

Anxiety

##### Timepoint

Before and after the intervention, the dilatation was measured at 6 - 7 and 9- 7.

##### Method of measurement

Spielberger Anxiety Inventory

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: Conducting a CD of guided imagery for 18 minutes through headphones that included beautiful or pleasant landscapes.

##### Category

Placebo

**2**

**Description**

Control group: Only routine care was performed for the control group

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

22 Bahman Hospital, Gonabad

**Full name of responsible person**

Dr. Mohsen Saheb Maleki

**Street address**

Nasir Khosrow Street

**City**

Gonabad

**Province**

Razavi Khorasan

**Postal code**

9691793718

**Phone**

+98 51 5722 0576

**Email**

info@gmu.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

Dr. shahla khosravan

**Street address**

Asian Roads, Gonabad University of Medical Sciences,  
Student Research Committee

**City**

Gonabad

**Province**

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**Postal code**

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**Phone**

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**Email**

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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**

Gonabad 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**

Gonabad University of Medical Sciences

**Full name of responsible person**

Iman Ghorbany Moghaddam

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No9, Behesht Street, Emam Sajjad Blvd, Gonabad  
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imanghorbany135213@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Gonabad University of Medical Sciences

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## Person responsible for updating data

### Contact

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Gonabad University of Medical Sciences

**Full name of responsible person**

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Razavi Khorasan

**Postal code**

9691793718

**Phone**

## 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**

Not applicable

**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