

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 polyhydramnios 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

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9691793718

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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

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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

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Person responsible for updating data

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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