

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of Benson relaxation and non-verbal music on anxiety in pregnant mothers before cesarean section

Protocol summary

Study aim

Determining the effect of Benson relaxation and non-verbal music on mothers anxiety before cesarean surgery in selected hospitals in Karaj

Design

A clinical trial with a control group, with parallel groups, one-blind, with a sample size of 105 people, which are divided into three groups of Benson relaxation, non-verbal music and control by simple random assignment

Settings and conduct

The research environment is selected hospitals in Alborz province in which cesarean section is performed and includes Bamonar, Rajaei, Kamali, Sarollah and Alborz hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: full consciousness; ability to read and write; experience of first cesarean section; having a doctor's license. Non- Inclusion criteria: unwillingness to cooperate; hearing impairment; mental and anxiety disorders; history of chronic pain and cancer; experience of stress in the last 3 months; Use of herbal or chemical sedatives.

Intervention groups

In the intervention group, one hour before the cesarean section, Benson's muscle relaxation recorded in tape will be played through the Walkman and headphones for 20 minutes, and the subjects will be asked to perform relaxation according to the instructions in the tape. In the non-verbal music will be played for 20 minutes via Walkman and the headphone. Control group participants receive only routine nursing care

Main outcome variables

Anxiety

General information

Reason for update

Add control group

Acronym

IRCT registration information

IRCT registration number: **IRCT20190408043199N1**

Registration date: **2020-08-29, 1399/06/08**

Registration timing: **prospective**

Last update: **2022-01-01, 1400/10/11**

Update count: **1**

Registration date

2020-08-29, 1399/06/08

Registrant information

Name

sedigheh nosrati Abarghoee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3434 9805

Email address

pajohesh3584@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-20, 1400/10/30

Expected recruitment end date

2022-04-19, 1401/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Benson relaxation and non-verbal music on anxiety in pregnant mothers before cesarean section

Public title

Relaxation effect on anxiety in mothers before cesarean section

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Full consciousness Ability to read and write Experience the first cesarean section Have a doctor's license

Exclusion criteria:

Reluctance to cooperate Hearing impairments Mental and anxiety disorders History of chronic pain and cancer Experience stress in the last three months Use of herbal or chemical sedatives

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are randomly divided into three groups: Benson Relaxation, Music Therapy, and Control, using the card shuffle method. First, code A is given to the Benson group, code B to the music group, and code C to the control group. The letters A, B or C are then written on the cards and placed in the envelope. Each participant is then asked to choose one of the envelopes. Participants who choose A, B, or C enter the Benson, Music, and Control groups, respectively.

Blinding (investigator's opinion)

Single blinded

Blinding description

A statistician who is blinded by a group assignment will perform the analysis using SPSS software

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Alborz University of Medical Sciences

Street address

Deputy of Research and Technology; Safariyan alley; Ghehelo Pang Metri Golshahr

City

Karaj

Province

Alborz

Postal code

3198764653

Approval date

2019-01-12, 1397/10/22

Ethics committee reference number

ABZUMS.REC.1397.163

Health conditions studied**1****Description of health condition studied**

Scary anxiety before section

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Anxiety

Timepoint

Before surgery and immediately after the intervention

Method of measurement

Spielberger Situational Anxiety Inventory

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In the intervention group, one hour before cesarean section, the Benson muscle relaxation method will be recorded on a tape through a walkman and headphones for 20 minutes and people will be asked. Perform the relaxation procedure according to the instructions in the bar.

Category

Lifestyle

2**Description**

In the non-verbal music group will be played for 20 minutes through a walkman and headphones.

Category

Lifestyle

3**Description**

Control group: Participants in the control group only receive routine nursing care.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali hospital

Full name of responsible person

Sedigheh Nosrati Abarghoee

Street address

Kamali Educational Center; Kamali street; Shohada square; Shahid Beheshti street

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3134877179

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+98 26 3222 2021

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pajohesh3584@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Dr Mohamad Norisepehr

Street address

Deputy of Research and Technology; Safariyan alley; Ghehelo Pang Metri Golshahr

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3198764653

Phone

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Email

Research@abzums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Sedigheh Nosrati Abarghoee

Position

Non-faculty

Latest degree

Master

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Non-faculty

Latest degree

Master

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available