Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Bahonar, 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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Karaj

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3134877179

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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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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

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Position

Non-faculty

Latest degree

Master

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Person responsible for updating data

Contact

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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