

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of relaxation technique on anxiety and hemodynamic parameters in women before cesarean section

Protocol summary

Study aim

Determining the effect of Benson relaxation method on anxiety and hemodynamic parameters in women before cesarean section

Design

It is a two-group clinical trial in which the study population consists of all mothers waiting for cesarean section.

Settings and conduct

Receiving face-to-face relaxation training by the researcher to hospitalized mothers waiting for cesarean section and listening to the relaxation audio file at least 3 times before cesarean section Bahar and Khatam Al-Anbia Educational, Research and Treatment Centers

Participants/Inclusion and exclusion criteria

All mothers waiting for cesarean section who are at least 18 and at most 36 years old, have no hearing loss, muscle paralysis, thyroid disorder, known mental illness and previous history of cesarean section and similar courses of muscle relaxation, sedative use in the last 24 hours and ability to understand Persian language and obtaining an anxiety score of 7 and above from the hospital anxiety tool.

Intervention groups

Intervention group of 31 people (routine care with relaxation)

Main outcome variables

Anxiety; blood pressure; Pulse rate; Number of breaths

General information

Reason for update

The change in the sample size is due to the change in the conditions of inclusion in the study of this edition.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200718048128N1**

Registration date: **2020-08-05, 1399/05/15**

Registration timing: **retrospective**

Last update: **2024-09-07, 1403/06/17**

Update count: **1**

Registration date

2020-08-05, 1399/05/15

Registrant information

Name

Mansoure Kheiri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-02, 1397/10/12

Expected recruitment end date

2019-07-03, 1398/04/12

Actual recruitment start date

2019-01-02, 1397/10/12

Actual recruitment end date

2020-01-02, 1398/10/12

Trial completion date

2020-01-02, 1398/10/12

Scientific title

The effect of relaxation technique on anxiety and hemodynamic parameters in women before cesarean section

Public title

The effect of Benson relaxation technique on anxiety and hemodynamic parameters in women before cesarean section

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All mothers are waiting for a cesarean section

Exclusion criteria:

History of previous cesarean section

Age

From **18 years** old to **36 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **62**

Actual sample size reached: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples of this study included 62 eligible mothers with the consent of participating in the study, based on the allocation sequence produced by block method in volume 4, were randomly assigned to the study and control groups. For secrecy of the allocation sequence, since the two sample centers were collected simultaneously, the central secrecy method was used. Thus, the allocation sequence was in the hands of an individual outside the research team, and the relevant expert in each center, after registering the participants for the allocation of each individual, contacted the individual and assigned the participant to the intervention or control group.

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 Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences and Health Services, Haftam Tir Square

City

Shahroud

Province

Semnan

Postal code

36147073947

Approval date

2016-12-21, 1395/10/01

Ethics committee reference number

IR.SHMU.REC.1395.101

Health conditions studied

1

Description of health condition studied

cesarean section

ICD-10 code

P03.4

ICD-10 code description

Newborn (suspected to be) affected by Cesarean delivery

Primary outcomes

1

Description

Anxiety

Timepoint

The experimental group listened to the audio file of the relaxation training for 6 minutes and at least 3 times before the operation, 3-5 hours before cesarean section (the beginning of relaxation training is from the beginning of the morning, which does not interfere with the patient's sleep). He will practice Benson according to the instructions on the relaxation bar.

Method of measurement

Hospital Anxiety and Depression Scale (Anxiety Questions Only) and Hemodynamic Information Form

Secondary outcomes

1

Description

Hemodynamic indicators

Timepoint

The experimental group listened to the audio file of the relaxation training for 6 minutes and at least 3 times before the operation, 3-5 hours before cesarean section (the beginning of relaxation training is from the beginning of the morning, which does not interfere with the patient's sleep). He will practice Benson according to the instructions on the relaxation bar.

Method of measurement

Hemodynamic information form

Intervention groups

1

Description

Intervention group: All mothers waiting for cesarean section admitted to the educational-medical center (routine care with relaxation). The intervention group, after receiving face-to-face training of the relaxation method by the researcher and gaining the researcher's

confidence in learning this method, listened to an audio file of relaxation training 3-5 hours before cesarean section and at least 3 times before cesarean section according to the instructions. Spread on a Benson muscle relaxation tape will practice (start relaxation training early in the morning that does not interfere with the patient's sleep)

Category

Behavior

2**Description**

Control group: The control group also receives routine ward care.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Bahar Educational, Research and Treatment Center

Full name of responsible person

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2**Recruitment center****Name of recruitment center**

Khatam Al-Anbia Hospital (PBUH) Shahroud

Full name of responsible person

Mansoure kheiri

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University Boulevard - in front of the University of Technology - Khatam Al-Anbia One Hundred Bed Hospital (PBUH)

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahroud University of Medical Sciences

Full name of responsible person

Dr Hamid Kalalian

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Deputy of Management and Resources Development, Alborz Building, Corner of Ayatollah Behjat St., Fazlollah Nouri Blvd., Alborz Tow

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h.kalalian@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahroud 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**

Shahroud University of Medical Sciences

Full name of responsible person

Mansoure Kheiri

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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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

It has not been in the methodology.

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