

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effect of Benson's relaxation technique on anxiety and stress before Cesarean delivery in primiparous women

Protocol summary

Study aim

The effect of benson's relaxation technique on anxiety and stress before cesarean delivery in primiparous women

Design

clinical trial with two intervention and control groups and a volume of 60 samples

Settings and conduct

Research environment is maternity ward in imam hossein educational therapy center, affiliated to shahid beheshti university tehran It consists of 40 active beds. After obtaining the necessary permissions first, to select patients from both groups From afternoon the day before the operation The list of patients undergoing cesarean section surgery The next day will be referred And after obtaining satisfaction from the samples, Samples are based on paired and individual dates Will be allocated to intervention and control groups. In the Benson relaxation group units How to use the relaxation method They are taught Repeat it at least twice before surgery And in the control group routine care No relaxation method is done.

Participants/Inclusion and exclusion criteria

Criteria for entering :The originality of the samples - Candidates for cesarean samples - Having reading and writing skills - Full consciousness - Not having a history of psychiatric problems, seizures or epilepsy and severe heart failure approved by the doctor - Desire to attend relaxation sessions. Non-entry criteria: Patient's personal desire for not participating in the study Use of sedative and anxiety medications The candidate for normal delivery Emergency cesarean section (non-elective) High-risk pregnancy

Intervention groups

The intervention group is a group whose benson relaxation method runs on them. In the control group, routine care is performed without a relaxation method.

Main outcome variables

Providing comfort and satisfaction for patients; Assisting

clinical nursing tasks; The Importance of anxiety and stress control ; Increased satisfaction of patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170819035775N2**

Registration date: **2018-05-16, 1397/02/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-16, 1397/02/26**

Update count: **0**

Registration date

2018-05-16, 1397/02/26

Registrant information

Name

akram salmanzade

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Country

Iran (Islamic Republic of)

Phone

+98 212218008392

Email address

ak.salmanzade@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Benson's relaxation technique on anxiety and stress before Cesarean delivery in primiparous women

Public title

effect of relaxation on anxiety and stress

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Criteria for entering the study: - The originality of the samples - Candidates for cesarean samples - Having reading and writing skills - Full consciousness - Not having a history of psychiatric problems, seizures or epilepsy and severe heart failure approved by the doctor - Desire to attend relaxation sessions

Exclusion criteria:

The patient's personal desire to not participate in the study from the beginning Use of sedative and anti-anxiety medications by the patient The candidate for normal delivery of the patient Maternal delivery by emergency cesarean section (non-elective) High-risk pregnancy to confirm doctors

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Not randomized

Randomization description**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 University of Social Welfare and

Rehabilitation Sciences Tehran

Street address

Childhood stalemate, Student Boulevard, Evin, Tehran Town

City

Tehran

Province

Tehran

Postal code

۱۹۸۵۷۱۳۸۳۴

Approval date

2017-12-22, 1396/10/01

Ethics committee reference number

ir.uswr.rec.1396.280

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

Anxiety

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

stress

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

Stress Score in Kuhn's Perceived Stress Questionnaire

Timepoint

Before the intervention and one day after the intervention

Method of measurement

Using Cohen's Perceived Stress Questionnaire

2**Description**

Anxiety Scale in Spielberger's Clear Anxiety Inventory

Timepoint

Before the intervention and one day after the intervention

Method of measurement

Using Spielberger's Clear Anxiety Inventory

Secondary outcomes

empty

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

Samples are based on paired and individual dates, in both groups, they will intervene and control. The number of samples was divided into two intervention and control groups includes 60 people which was 30 in the intervention group and 30 people in the control group. Both in the intervention group and in the control group to measure the severity of anxiety and stress of patients at the beginning of hospitalization anxiety and stress questionnaires are given to the patient who are overwhelmed. Then after admission in the intervene group how to use Benson's relaxation method they are taught repeat it at least twice before surgery. In this study, the Benson relaxation is as follows the patient is in the best condition in which he feels calm in the bed, closes his eyes, in this case, choose the word that always reminds her of calm and begin to breathe deeply and regularly and he's done the nose and expelled exhale through the mouth and in every exhale repeats the word in mind. At the same time, the muscles are released from the tip of your toes and this continues to the upper muscles of the body so that all muscles can reach full expansion. The patient maintains this condition for 10 to 20 minutes. Then it is recommended to the patient that avoid changing mode and displacement immediately after the end of the technique. Intervention for each patient twice and every 15 minutes it takes place at intervals of 2 hours. The day of operation in the intervention group again anxiety and stress questionnaires is given to complete the samples half an hour before entering the operating room.

Category

Other

2

Description

Control group: In the control group, routine care wards will be taken without any additional care by researcher and on behalf of the medical staff which is related to research and without a relaxation technique. In the control group, only the samples which includes 30 people received anxiety and stress questionnaires twice, one time before admission and once upon a day, and they complete half an hour before going to the operating room.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Medical Center, Educational and Therapeutic Center

Full name of responsible person

Akram Salmanzadeh

Street address

Martyr Madani Street, Imam Hossein Hospital

City

Tehran

Province

Tehran

Postal code

47857

Phone

+98 21 7343 2527

Email

info@ehmc.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Hamidreza Khankeh

Street address

Childhood Death, Student Blvd, Evin, University of Social Welfare and Rehabilitation Sciences Tehran

City

Tehran

Province

Tehran

Postal code

۱۹۸۵۷۱۳۸۳۴

Phone

+98 21 2218 0083

Email

a.salmanzade94@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Akram Salmanzadeh

Position

Master's student of psychiatric nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Binjerabadi Alley, Behtashsefat street, Masoodieh

City

Tehran

Province

Tehran

Postal code

1787744641

Phone

+98 21 3345 2736

Email

a.salmanzade94@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

University of social welfare and rehabilitation sciences

Full name of responsible person

Akram Salmanzadeh

Position

Master's student of psychiatric nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Binjerabadi Alley, Behtashsefat Street, Masoodieh

City

Tehran

Province

Tehran

Postal code

1787744641

Phone

+98 21 3345 2736

Email

a.salmanzade94@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

University of social welfare and rehabilitation sciences

Full name of responsible person

Akram Salmanzadeh

Position

Master's student of psychiatric nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Binjerabadi Alley, Behtashsefat Street, Masoodieh

City

Tehran

Province

Tehran

Postal code

1787744641

Phone

+98 21 3345 2736

Email

a.salmanzade94@gmail.com

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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

pdf file informed consent form participation in research project

When the data will become available and for how long

Start the access period one year after the print results

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

Allow full use of the form

From where data/document is obtainable

Refer to email: a.salmanzade94@gmail .com

What processes are involved for a request to access data/document

After receiving the request via email within one to two weeks the form is sent to them.

Comments