Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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

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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

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Postal code

۱۹۸۵۷۱۳۸۳۴

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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
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Binjerabadi Alley, Behtashsefat street, Masoodieh
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Person responsible for scientific inquiries

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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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
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