

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The comparison of Teach Back educational method and accompanying person on anxiety and vital signs changes in woman candidate for cesarean section

Protocol summary

Summary

The purpose of this clinical trial is comparison between effectiveness of Teach Back method and accompanying person on anxiety level and vital signs in women undergo cesarean section. Inclusion criteria : age 20 to 30 years old, not treated with anxiolytic or sedative drugs during hospitalization, have consent to participate in the study and have moderate(41-60) or severe(61-80) anxiety according to the STAI and candidate for the first cesarean section. Exclusion criteria : psychological disorders, hearing loss, and unwillingness to continue participation in the study. Population of the study included all primiparous women undergoing cesarean section and The sample size included 90 primiparous women undergoing cesarean section. In this study, patients according to inclusion criteria were selected and randomly divided in three groups (2 groups of cases and 1 control group): group 1; were educated with teach back method in the night before their surgery, group 2; accompanying person were present in the ward from the night before their surgery until 15 minute to the start of surgery and group 3; was control group that received routine care. Anxiety levels and vital signs were evaluated before and after intervention by using Spiel Berger State-Trait Anxiety (STAI) Inventory. The effect of Teach Back method and Accompanying person on anxiety level and vital sign situation will be measured.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2014041417270N1**

Registration date: **2014-10-29, 1393/08/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-10-29, 1393/08/07

Registrant information

Name

Nasim Hatefi Moadab

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 918 728 2886

Email address

hatefi.n@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2014-07-05, 1393/04/14

Expected recruitment end date

2014-09-05, 1393/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of Teach Back educational method and accompanying person on anxiety and vital signs changes in woman candidate for cesarean section

Public title

The comparison of Teach Back educational method and accompanying person on anxiety and vital signs changes in woman candidate for cesarean section

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age 20 to 30 years old, not treated with anxiolytic or sedative drugs during hospitalization, have consent to participate in the study have moderate(41-60) or severe(61-80) anxiety according to the STAI and candidate for the first cesarean section. Exclusion criteria: psychological disorders, hearing loss, and unwillingness to continue participation in the study.

Age

From **20 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

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

Ahvaz Jundishapur University of Medical Sciences
Ethics Committee

Street address

Ahvaz Judishapur University of Medical Sciences,
Golestan highway, Ahvaz, Iran

City

Ahvaz

Postal code

Approval date

2014-10-07, 1393/07/15

Ethics committee reference number

ajums.REC.1393.216

Health conditions studied

1

Description of health condition studied

surgical anxiety

ICD-10 code

F40, F41,

ICD-10 code description

Neurotic, stress-related and somatoform disorders

Primary outcomes

1

Description

anxiety before surgery

Timepoint

the night before surgery and the day of the surgery

Method of measurement

Spiel Berger State-Trait Anxiety inventory

Secondary outcomes

1

Description

Systole Blood Pressure

Timepoint

Night Before The Surgery (Before Intervention)and Day
of The Surgery(After Intervention)

Method of measurement

mmHg- Electronic Manometer(Beurer made in Germany)

2

Description

Diastole Blood Pressure

Timepoint

Night Before The Surgery (Before Intervention)and Day
of The Surgery(After Intervention)

Method of measurement

mmHg- Electronic Manometer(Beurer made in Germany)

3

Description

Respiratory Rate

Timepoint

Night Before The Surgery (Before Intervention)and Day
of The Surgery(After Intervention)

Method of measurement

Number in minute by using analog clock and numeration

4

Description

Pulse Rate

Timepoint

Night Before The Surgery (Before Intervention)and Day
of The Surgery(After Intervention)

Method of measurement

Number in minute by using analog clock and numeration

5

Description

Temperature

Timepoint

Night Before The Surgery (Before Intervention)and Day of The Surgery(After Intervention)

Method of measurement

Mercury thermometer made in iran

Intervention groups

1

Description

second intervention group is the Accompanying Person group.In this group, routine training provided by the ward nurse and their partner were allowed to present next to them from the night before the surgery until 15 minutes before starting their surgery in the operating room.

Category

Prevention

2

Description

First intervention group is the Teach Back group. In this group individuals were educated by using Teach Back method in this way that after determining training needs, educational program that is approved by the faculty, provided by researcher. In this method, researcher visits the patients at the night before their surgery and educates them face-to-face, in simple and understandable terms without use of special medical training terms in 45-30 minute. After completion of training, the patient were asked to say what they understand, in their own words. If the patient has not understood the content of sessions, educator would continue to explain until the patient would fully understand the contents. this educational program has a regular structure and Is flexible to suit the patient's needs that contains an overview of cesarean section include Reasons for Cesarean delivery, cesarean section maternal care, events are expected in the operating room and so on. To implement the method, face to face training will be used to raise the level of patient knowledge. One hour after training, the patient will be referred for evaluation of feedback and the patient's problems and questions will be answered. The Teach-Back score is set so that if the patient has 75% correct answers to the questions asked, it is considered an effective means of teaching and learning will continue otherwise.

Category

Prevention

3

Description

Control group is the third group whom no intervention applied to them except routine educations.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital in Abadan

Full name of responsible person

Nasim Hatefi Moadab

Street address

Faculty of Nursing, Taleghani Hospital Educational Complex, Abadan, Iran

City

Abadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Bahram Ebdali

Street address

Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Nasim Hatefi Moadab

Position

Student of Medical Surgical Nursing in M.S

Other areas of specialty/work

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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Nasrin Elahi

Position

Group manager/Phd

Other areas of specialty/work**Street address**

Faculty of Nursing, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

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

Abadan School of Medical Sciences

Full name of responsible person

Khadije Moradbeygi

Position

Member of Faculty In Abadan School of Medical Sciences

Other areas of specialty/work**Street address**

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-

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khadijemoradbeygi@yahoo.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty