

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The effect of training using virtual reality (VR) method on the anxiety of patients before cesarean section

Protocol summary

Study aim

The effect of training using virtual reality (VR) method on the anxiety of patients before cesarean section

Design

This clinical trial study has a control group with one-way blinded parallel groups and is conducted on 70 patients.

Settings and conduct

Study is conducted in Imam Ali Chabahar Hospital. The process of educating patients in this study is implemented in three steps: 1. Compilation of the educational scenario and filming with a 360-degree camera 2. Playing a 360-degree educational video with virtual reality glasses for the intervention group and routine training for the control group 3. Before training and after training, evaluation with a questionnaire

Participants/Inclusion and exclusion criteria

The entry criteria are being in the age range of 18 to 45, having consent, and the exit criteria being emergency cesarean surgery, history of drug use, history of surgery, and cardiovascular and nerve diseases.

Intervention groups

The intervention group includes patients who are candidates for non-emergency cesarean surgery. The researcher explains the objectives of the study and after obtaining their consent to participate in the research, the patient's demographic questionnaire is completed using an interview, and then the intervention group is given the night before the operation in the gynecologist's office, a 360-degree educational video with virtual reality glasses for the patient. will be broadcasted, also for the control group, routine training will be given before the operation.

Main outcome variables

anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230409057865N1**

Registration date: **2023-06-20, 1402/03/30**

Registration timing: **prospective**

Last update: **2023-06-20, 1402/03/30**

Update count: **0**

Registration date

2023-06-20, 1402/03/30

Registrant information

Name

masoumeh mobaraki

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 915 840 5155

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-20, 1402/04/29

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of training using virtual reality (VR) method on the anxiety of patients before cesarean section

Public title

The effect of training using virtual reality (VR) method on the anxiety of patients before cesarean section

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Being in physical condition (ASA) 1 and 2 graded by American Anesthesiologists Being in the age range of 18-45 years Consent to participate in the study

Exclusion criteria:

The emergency of cesarean surgery History of taking anti-anxiety and sedative drugs History of cesarean surgery History of heart, nervous and mental diseases, uncontrolled blood pressure, eclampsia Women who are members of the hospital staff

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The random selection of the intervention and control groups is simple random. Flip the coin method is used, based on the sample size, the same number of coins are thrown and people are randomly assigned to two groups. This random selection is obtained from the patients admitted to the gynecologist's office.

Blinding (investigator's opinion)

Single blinded

Blinding description

The interviewer does not know the type of intervention and control group to assess the level of anxiety with a questionnaire. and records the answer according to the patient's answer.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iranshahr University of Medical Sciences

Street address

Shahid Moradi Blvd, Iranshahr University of Medical Sciences

City

Iranshahr

Province

Sistan-va-Balouchestan

Postal code

9913743137

Approval date

2022-08-20, 1401/05/29

Ethics committee reference number

IR.IRSHUMS.REC.1401.028

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

anxiety

Timepoint

24 hours before the intervention - one hour after the intervention

Method of measurement

Amsterdam anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The night before the operation, in the gynecologist's office, training is given on how to use virtual reality glasses, and a 360-degree educational video with virtual reality glasses is played for the patient, the content of a complete virtual reality tour in Persian and local (Baluchi) languages. The preparation time is 10 minutes and its scenario is designed based on the standards of patient education and the patient's legal charter. The Amsterdam questionnaire is completed one hour before the procedure.

Category

Treatment - Devices

2

Description

Control group: for the control group, routine training will

be given before cesarean section.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Ali hospital, Chabahar city

Full name of responsible person

Masoumeh Mobaraki

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranshahr University of Medical Sciences

Full name of responsible person

Abbas Balouchi

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No. 46 ,Emam khomeini Ave , Iranshahr city

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iranshahr 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

Iranshahr University of Medical Sciences

Full name of responsible person

Masoumeh Mobaraki

Position

Faculty instructor

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

Not applicable

Data Dictionary

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