

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 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)

##### Phone

+98 915 840 5155

##### Email address

m.mobaraki@irshums.ac.ir

#### 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

**Street address**

Qods Blvd

**City**

chabahar

**Province**

Sistan-va-Balouchestan

**Postal code**

99719 43311

**Phone**

+98 54 3533 3016

**Email**

info@irshums.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Iranshahr University of Medical Sciences

**Full name of responsible person**

Abbas Balouchi

**Street address**

No. 46 ,Emam khomeini Ave , Iranshahr city

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**Email**

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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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**Latest degree**

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**Latest degree**

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**Other areas of specialty/work**

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masum547@yahoo.com

**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