

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The effect of virtual reality on physiological indices and anxiety of patients before wisdom tooth surgery

#### Protocol summary

##### Study aim

Evaluation the effect of virtual reality on physiological indices and anxiety of patients before wisdom tooth surgery

##### Design

In this research, the samples were selected by a goal-based method of 60 people and then assigned randomly to two groups of intervention (30 people) and control (30 people).

##### Settings and conduct

Patients Candidate for wisdom tooth surgery in Mashhad Dentistry School. Operation in Mashhad Dentistry School

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient's willingness to participate in the study with informed consent The age range of 18-35 years Having the necessary visual and auditory ability Have the ability to read and write in Persian Exclusion criteria: History of diagnosed mental illness, cardiovascular disease (myocardial infarction, hypertension, cardiac arrhythmia) History of diagnosed respiratory illnesses and disorders are Using the drugs that affect heart and mind and breathing Previous history of previous surgery

##### Intervention groups

Intervention group: The tool used for virtual reality technique is a virtual reality headset device, a film about nature with high quality waterfall images and sounds in a 10 minute before the surgery. Control group: Receive routine care similar to intervention group without any special intervention (VR).

##### Main outcome variables

Anxiety. Physiological indices(blood pressure, pulse rate, rate and rhythm of inspiratory)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181023041425N1**

Registration date: **2020-03-13, 1398/12/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-03-13, 1398/12/23**

Update count: **0**

##### Registration date

2020-03-13, 1398/12/23

##### Registrant information

###### Name

Majid Hosseini Abrishami

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3882 9501

###### Email address

hoseiniabrishamim@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-09, 1398/12/19

##### Expected recruitment end date

2020-05-18, 1399/02/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of virtual reality on physiological indices and anxiety of patients before wisdom tooth surgery

##### Public title

The effect of virtual reality on anxiety of patients before

wisdom tooth surgery

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Patient's willingness to participate in the study with informed consent  The age range of 18-35 years  Having the necessary visual and auditory ability  Have the ability to read and write in Persian

**Exclusion criteria:**  
History of diagnosed mental illness, cardiovascular disease (myocardial infarction, hypertension, cardiac arrhythmias) History of diagnosed respiratory illnesses and disorders are Using the drugs that affect heart and mind and breathing Previous history of previous surgery

**Age**  
From **18 years** old to **35 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **60**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
First patients will be selected purposefully based on inclusion criteria and then are allocated into intervention and control groups by simple randomization (sortition and alternately).

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
1- Associate researcher who measures anxiety and physiological indices waits for the patients in a specific room and he is blinded about patients groups. In order to prevent bias, each of people are guided to this room and their anxiety and physiological indices will be measured and written down. 2-The analyser does not know about each of groups data (intervention and control groups).

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical

Sciences  
**Street address**  
No. 20, Mahdi. 1 Ave., Valiasr Blvd., Gonabad Town  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
96919119735  
**Approval date**  
2019-07-01, 1398/04/10  
**Ethics committee reference number**  
IR.MUMS.DENTISTRY.REC.1398.020

## Health conditions studied

### 1

#### Description of health condition studied

wisdom tooth surgery

#### ICD-10 code

Z98.818

#### ICD-10 code description

Other dental procedure status

## Primary outcomes

### 1

#### Description

physiological indices and anxiety before surgery

#### Timepoint

10 minutes before and after intervention

#### Method of measurement

Spielberger scale and physiological indices form, Monitoring system

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In this group, consent form and demographic information questionnaire will be completed. Then we measure anxiety and physiological indices. Patients use virtual reality technique (includes a system and headset with high quality) for 10-15 minutes before injection. Then anxiety and physiological indices are measured again and the surgery is done.

#### Category

Other

### 2

#### Description

Control group: In this group, all the steps explained in the intervention group will be done except using virtual reality system. Patients Wait for surgery without

intervention(VR) and anxiety and physiological indices are measured again exactly like the previous group.

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Mashhad Dentistry School

**Full name of responsible person**

Hoseini Abrishami Majid

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<http://dentistry.mums.ac.ir>

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hoseini Bagheri (Research Chancellor)

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BagheriH@mums.ac.ir

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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**

Mashhad University of Medical Sciences

**Proportion provided by this source**

70

**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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hoseini Abrishami Majid

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Hoseini Abrishami Majid  
**Position**  
Assistant Professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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HoseiniAbrishamiM@mums.ac.ir  
**Web page address**  
<http://dentistry.mums.ac.ir>

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is 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

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

### Title and more details about the data/document

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### When the data will become available and for how long

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### To whom data/document is available

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### Under which criteria data/document could be used

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### From where data/document is obtainable

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

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### Comments

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