Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 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 indicies 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 indicies will be measured and written down. 2-The analyser does not khnow 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 indicies. Patients use virtual reality technique (includes a system and headset with high quality) for 10-15 minutes before injection. Then anxiety and physiological indicies 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 indicies 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

Street address
No. 20, Mahdi. 1 Ave., Valiasr Blvd., Gonabad Town

City
Mashhad

Province
Razavi Khorasan

Postal code
96919119735

Phone
+98 51 3882 9502

Fax
+98 51 3882 9500

Email
HoseiniAbrishamiM@mums.ac.ir

Web page address
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)

Street address
No. 20, Mahdi. 1 Ave., Valiasr Blvd., Gonabad Town

City
Mashhad

Province
Razavi Khorasan

Postal code
96919119735

Phone
+98 51 3882 9502

Fax
+98 51 3882 9500

Email
BagheriH@mums.ac.ir

Web page address
http://dentistry.mums.ac.ir

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

Street address
No. 20, Mahdi. 1 Ave., Valiasr Blvd., Gonabad Town

City
Mashhad

Province
Razavi Khorasan

Postal code
96919119735

Phone
+98 51 3882 9501

Fax
+98 51 3882 9500

Email
HoseiniAbrishamiM@mums.ac.ir

Web page address
http://dentistry.mums.ac.ir

Person responsible for scientific 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

Street address
No. 20, Mahdi. 1 Ave., Valiasr Blvd., Gonabad Town

City
Mashhad

Province

Razavi Khorasan

Postal code
96919119735

Phone
+98 51 3882 9501

Fax
+98 51 3882 9500

Email
HoseiniAbrishamiM@mums.ac.ir

Web page address
http://dentistry.mums.ac.ir

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
Dentistry

Street address
No. 20, Mahdi. 1 Ave., Valiasr Blvd., Gonabad Town

City
Mashhad

Province
Razavi Khorasan

Postal code
96919119735

Phone
+98 51 3882 9502

Fax
+98 51 3882 9500

Email
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
--

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

To whom data/document is available
--

Under which criteria data/document could be used
--

From where data/document is obtainable
--

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

Comments
--