

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of virtual reality headsets on reducing pain and anxiety in patients during implant surgery in dentistry

Protocol summary

Study aim

Determining the effectiveness of virtual reality glasses on pain and anxiety control of patients

Design

A double-blind, crossover and controlled clinical trial with two experimental groups where both groups participated in both the experimental and control conditions. This study was conducted on 73 patients and randomization was done by List Randomizer software.

Settings and conduct

This study was conducted in the field of anxiety and pain control in the field of dentistry at Kermanshah University of Medical Sciences. Participants and presenters were blinded with the List Randomizer software. Then, the patients of the first group underwent their dental implant surgery using virtual reality glasses, and in the second session, they underwent surgery without glasses. The second group had the opposite process of the first group.

Participants/Inclusion and exclusion criteria

The condition for entering the study is to be a candidate to receive an implant and the condition for leaving it is not to be interested in participating in the trial

Intervention groups

In this study, Kennedy class 1 mandibular edentulous patients who are candidates for implants will be used. 80 patients between 25 and 55 years of age participate in this study. All patients require dental implants in both 6 mandibular teeth, and this process will be performed for each patient in two sessions, one week apart. Virtual reality glasses will be used in half of the patients in the first week, and implant surgery will be done for them in the second week without glasses and under the control group. In the other 50% of patients, the treatment will be done without glasses first, and then in the next week, the treatment will be done with virtual reality glasses. Factors of Pain, Anxiety, Satisfaction and Vividness of memories will be examined in each patient.

Main outcome variables

Pain, Anxiety, Satisfaction, Vividness of memories

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230612058461N1**

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

Alireza Ghobadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3424 2296

Email address

alireza.ghobadi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-01, 1402/04/10

Expected recruitment end date

2023-07-08, 1402/04/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of virtual reality headsets on reducing pain and anxiety in patients during implant surgery in dentistry	
Public title	The effect of Virtual reality headsets on reducing pain and anxiety in implant
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Being a suitable candidate for implant surgery
Exclusion criteria:	
Age	From 18 years old
Gender	Both
Phase	N/A
Groups that have been masked	• Participant • Care provider • Investigator • Outcome assessor • Data analyser
Sample size	Target sample size: 45
Randomization (investigator's opinion)	Randomized
Randomization description	Randomization was achieved using a list of numbers generated by the computer software List Randomizer. These numbers obtained from the previous section were generated by a blinded third-party statistician (someone who was not involved in screening, treatment, follow-up, data collection, or analysis) and were used to allocate participants to the two experimental groups. This information was hidden in sealed envelopes, which were opened before the surgical treatment.
Blinding (investigator's opinion)	Double blinded
Blinding description	A blinded third-party statistician (one who was not involved in screening, treatment, follow-up, data collection, or analysis) achieved two-way blinding of physician and patient using a list of numbers generated by the List Randomizer computer software. These obtained numbers were used to assign the participants to two experimental groups. This information will be kept in sealed envelopes, hidden and opened prior to surgical treatment.
Placebo	Not used
Assignment	Crossover
Other design features	
Secondary Ids	empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Ethics Committee., University Building No. 2., In front of Imam Ali (AS) Hospital., Shahid Beheshti Blvd., Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

6715745649

Approval date

2023-05-23, 1402/03/02

Ethics committee reference number

IR.KUMS.REC.1402.076

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

2

Description of health condition studied

Pain

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

Pain in the Visual Analogue Scale (VAS) questionnaire

Timepoint

Before and immediately after studying

Method of measurement

Visual Analogue Scale 0-10

2

Description

Anxiety in State-Trait Anxiety Inventory (STAI) variable

Timepoint

Before and immediately after studying

Method of measurement

Spielberger State-Trait Anxiety Inventory (STAI)

Secondary outcomes

1

Description

Vividness of memories

Timepoint

One week after studying

Method of measurement

Visual Analogue Scale 0-10

2

Description

Satisfaction

Timepoint

Immediately after studying

Method of measurement

Visual Analogue Scale 0-10

Intervention groups

1

Description

intervention group: in the first group of the experiment; Half of the patients undergo implant surgery for lower 6 teeth with VR in the second meeting, and in the third meeting, they undergo implant surgery for their other lower 6 teeth without VR. The average surgical procedure is 25 minutes. This time was without taking into account the time of patient preparation and anesthetic injection and waiting time for its effectiveness to start. In this project, the following questionnaires are used, and the time to use each of them is as follows. 1: NRS Questionnaire: This questionnaire is used at the beginning and end of the treatment session to measure the expected pain of the patient and the pain experienced after the treatment. , at the end of treatment to determine the level of patient satisfaction, at the end of treatment to determine the level of dentist satisfaction with the treatment process 2: STAI questionnaire: at the beginning of each treatment session to measure the level of anxiety of the patients' trait 3: MDAS questionnaire: at the beginning of each treatment session to measure the level of anxiety Dental patients. 4: Vividness on Memories telephone questionnaire: to check the extent to which patients recall memories 5: asking the patient to guess about the duration of the treatment process.

Category

Treatment - Devices

2

Description

intervention group: in the second group of the experiment and vice versa in the first group; First, the patients undergo implant surgery for lower 6 teeth without VR, and in the third meeting, they undergo implant surgery for their other lower 6 teeth with VR. All tests and experiments are completely similar to the first

intervention group.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah University of Medical Sciences

Full name of responsible person

Alireza Ghobadi

Street address

In front of the post office., Above Shura Street., Dr. Shariati Street., Kermanshah

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alirezaghobadi1376@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Vice President of Research and Technology of Kermanshah Faculty of Dentistry

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Grant name

Grant code / Reference number

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

No

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Alireza Ghobadi
Position
Student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It will be referred to it again in future studies

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

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