Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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+98 83 3424 2296

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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
Vividnss 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
Street address
In front of the post office., Above Shura St., Dr. Shariati St., Kermanshah
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6713954658
Phone
+98 83 3724 8531
Email
alirezaghobadi1376@yahoo.com
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 scientific inquiries

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Name of organization / entity

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Position

Student

Latest degree

Medical doctor

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Position

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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