

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

The effect of showing an educational video related to implant surgery on patients anxiety level

Protocol summary

Study aim

The effect of showing an educational video related to implant surgery on patients anxiety level

Design

We will use the Restricted Randomization method with blocks of six. The sample size is expected to be 60 people

Settings and conduct

Preparation of educational video This video is performed by a maxillofacial surgeon and the implant procedure is explained step by step Obtaining informed consent from these patients, randomly dividing patients into two intervention and control groups using random allocation of permuted blocks. An explanation about the research and the process of doing the work, then the completion of the relevant questionnaires by the subjects under study, which will be completed by the patient himself or his companion if they are literate, and by the researcher if they are not literate. For the control group, there is no intervention and the questionnaire is completed only on two occasions For all patients, basic instructions are given regarding the method of implant surgery The educational video will be shown to the intervention group on different days, and two groups will not visit on the same day. The relevant patients are completed The questionnaire is only explained to the patients by the relevant researcher For the control group, only the questionnaire is explained

Participants/Inclusion and exclusion criteria

Patients who are candidates for implant surgery for the first time and do not have a history of previous anxiety and do not have a systemic disease that interferes with implant surgery.

Intervention groups

In this study, an educational film is shown to the intervention group and its effect on the patient's anxiety is evaluated

Main outcome variables

Increase patient anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221114056499N1**

Registration date: **2022-11-30, 1401/09/09**

Registration timing: **prospective**

Last update: **2022-11-30, 1401/09/09**

Update count: **0**

Registration date

2022-11-30, 1401/09/09

Registrant information

Name

Ali Hematian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3333 5914

Email address

hematian_ali@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-21, 1401/09/30

Expected recruitment end date

2023-02-19, 1401/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of showing an educational video related to implant surgery on patients anxiety level

Public title

The effect of showing video on anxiety

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Candidates for implant surgery Need implant surgery for the first time Do not have complete information about implant surgery In general, the patient should not be anxious

Exclusion criteria:

The presence of systemic diseases that interfere with implant surgery Having information about implant surgery Have experience in implant surgery

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced random distribution: Our sample size is 60 people First, we consider 10 blocks of 6 people (that is, the process of random division is balanced for 6 patients) and from every 6 people who enter a block, we divide them into two groups, A and B, now all the situations that can be 3A and 3B I write to have, which can be 20 cases We determine the sampling numbers for each of the blocks because each block must have the same chance of selection as the others and the sampling numbers must be the same for all groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Semnan University of Medical Sciences

Street address

Semnan, Basij Blvd., Central Headquarters of Semnan University of Medical Sciences, Research and Technology Vice-Chancellor

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2022-10-09, 1401/07/17

Ethics committee reference number

IR.SEMUMS.REC.1401.184

Health conditions studied

1

Description of health condition studied

Implant surgery

ICD-10 code

F41.1

ICD-10 code description

Disorders of adult personality and behaviour

Primary outcomes

1

Description

Increase or Decrease anxiety

Timepoint

The level of anxiety is measured immediately before and after the video is shown

Method of measurement

The level of anxiety is measured by the Spielberger questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: an educational video is shown to this group, and immediately before and after the video is shown, the decrease or increase in the patient's anxiety level is measured by a questionnaire.

Category

Behavior

2

Description

Control group: Control group: only 2 questionnaires are filled for the patient, one in the first stage of cooking and the other before the operation

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Semnan University of Medical Sciences dental clinic

Full name of responsible person

Zahra Amiri

Street address

17 Shahrivar Blvd

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94431-35187

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Ava Nikbin

Street address

Headquarter of Semnan University of Medical Sciences and Health Services, Bassij Blvd, Semnan, Iran

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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

Semnan University of Medical Sciences

Proportion provided by this source

1

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

Semnan University of Medical Sciences

Full name of responsible person

Ali Hemmatian

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Ali Hemmatian

Position

student

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Person responsible for updating data

Contact

Name of organization / entity

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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

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