

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of educational video on preoperative anxiety of Phico-cataract patients

Protocol summary

Study aim

Determining the effect of short educational video on anxiety before cataract surgery by Fico method

Design

Clinical trial with control group, double-blind, 80 people in each group at random

Settings and conduct

After receiving the code of ethics from the research deputy, the researcher will refer to the Abu Reihan subspecialty clinic, and after obtaining the written informed consent of the research units, he will intervene. In this way, patients who met the inclusion criteria will be selected by simple random sampling and will be divided into two groups of test and control. After filling out the questionnaires, a 10-minute short training video on Fico surgery will be shown to the experimental group and explanations about Fico surgery will be given to the control group on a routine basis. On the day of surgery The researcher referred to the research environment again and completed the questionnaires 1 hour before the patient went to the operating room for phaco surgery.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Participants are both male and female, have full consent to participate in the study, the presence of the disease in them is confirmed by an ophthalmologist and patients with cataracts, familiar with the Persian language and the ability to read and write, in the range Are aged 75-20 years. Exclusion Criteria: Severe psychiatric disorders such as psychotic disorders and panic disorder, incurable physical diseases, History of drug use

Intervention groups

The intervention in the present study is a short educational video on anxiety before cataract surgery by Fico method. The control group receives routine preoperative care.

Main outcome variables

The anxiety of patients who are candidates for cataract

surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200115046145N1**

Registration date: **2020-09-05, 1399/06/15**

Registration timing: **retrospective**

Last update: **2020-09-05, 1399/06/15**

Update count: **0**

Registration date

2020-09-05, 1399/06/15

Registrant information

Name

Dorna Sattar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 0823

Email address

dornasattar@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-30, 1398/11/10

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational video on preoperative anxiety of Phico-cataract patients

Public title

The effect of educational video on preoperative anxiety in patients with cataract

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Participants are both male and female Have full satisfaction to participate in the research Have a file in the Abu Reihan subspecialty clinic in Tehran in the year 1997-98 The presence of the disease in them should be confirmed by an ophthalmologist and patients should have cataracts Familiar with Persian language and ability to read and write Be in the age range of 75-20 years

Exclusion criteria:

Severe psychiatric disorders such as psychotic disorders and bipolar disorder Having incurable physical diseases such as cancer History of drug use

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

The statistician, patients, and nurses who measured the variables were unaware of the randomization of the samples, so that patients only knew that they had participated in the study but did not know which group they belonged to. The data were also coded to the statistician and the type of group was not mentioned to the statistical analyzer, but the researcher was aware of the randomization of the samples. Therefore, two-way study is considered blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University of Medical Sciences, Tehran

Street address

Islamic Azad University of Tehran Medical Sciences Branch, Khaghani St, Shariati Ave

City

Tehran

Province

Tehran

Postal code

1916893813

Approval date

2019-11-20, 1398/08/29

Ethics committee reference number

IR.IAU.TMU.REC.1398.147

Health conditions studied

1

Description of health condition studied

Anxiety of patients undergoing cataract surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety score in Spielberger questionnaire

Timepoint

At the beginning of the study and one day after showing the short educational video (one hour before surgery)

Method of measurement

Spielberger Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention of the present study will be a short educational video (10 minutes) about cataract surgery by Fico method. The content of the educational video will be about how and when to perform fico surgery and pre- and post-operative care

Category

N/A

2

Description

Control group: The control group received only routine nursing care and was given the usual training on cataract surgery orally.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Abu Reihan Clinic of the Social Security Organization

Full name of responsible person

Dorna Sattar

Street address

Abu Reihan Clinic of the Social Security Organization,
Palestine St, Enghelab Ave,

City

Tehran

Province

Tehran

Postal code

1315794831

Phone

+98 21 6617 5379

Email

dornasattar@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Farshad Hashemian

Street address

Islamic Azad University of Medical Sciences Tehran,
Khaghani St, Shariati Av

City

Tehran

Province

Tehran

Postal code

1916893813

Phone

+98 21 2264 0599

Email

fhashemian@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Islamic Azad University of Medical Sciences, Tehran

Proportion provided by this source

100

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

Islamic Azad University

Full name of responsible person

Dorna Sattar

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Abu Reihan Clinic of the Social Security Organization,
Enghelab St, Palestine Ave

City

Tehran

Province

Tehran

Postal code

1315794831

Phone

+98 21 6617 5379

Fax

Email

dornasattar@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

dornasattar

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Abu Reihan Clinic of the Social Security Organization,
Palestine St, Enghelab Ave

City

Tehran

Province

Tehran

Postal code

1315794831

Phone
0098 66175379
Email
dornasattar@gmail.com

+98 21 6617 5379
Email
dornasattar@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Dorna Sattar
Position
Bachelor of Nursing
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Abu Reihan Clinic of the Social Security Organization,
Palestine St, Enghelab Ave
City
Tehran
Province
Tehran
Postal code
1315794831
Phone

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

There is no more information

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