

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparing the effects of familiarizing surgical process through watching videos, and visiting the operating environment on anxiety of elderly candidates for cataract surgery.

Protocol summary

Study aim

Comparing the effect of getting familiar with the cataract surgery process through watching the video and visiting the operating environment on the anxiety of the elderly.

Design

Patients will be assigned to three groups based on the inclusion criteria using the purpose-based sampling method and the three permutation block method. The interventions will be carried out in three study groups of 27 people as follows. the film screening group, the working environment visit group and the control group

Settings and conduct

. After the intervention, the Spielberger questionnaire will be completed by the researcher once a day before the surgery and again half an hour before the surgery in the inpatient department by the interview method. This study takes place in the operating room of Allameh Bohlool Hospital. Participant, evaluator and data analyzer are unaware of group assignment.

Participants/Inclusion and exclusion criteria

Willingness to participate in the study; not having a history of mental, cardiovascular, and respiratory disorders; age 60 years and older; no hearing impairment; no use of sedatives and beta-blockers; not having a previous history of cataract surgery; not having severe anxiety; unwillingness to continue participating; the occurrence of events that affect the patient's anxiety.

Intervention groups

Interventions will include showing the cataract surgery process video and visiting the surgery environment.

Main outcome variables

The anxiety of the elderly

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231206060275N1**

Registration date: **2024-02-05, 1402/11/16**

Registration timing: **prospective**

Last update: **2024-02-05, 1402/11/16**

Update count: **0**

Registration date

2024-02-05, 1402/11/16

Registrant information

Name

Akram Nami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5723 6331

Email address

eoc@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-06-04, 1403/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of familiarizing surgical process

through watching videos, and visiting the operating environment on anxiety of elderly candidates for cataract surgery.	
Public title	Comparing the effect of familiarizing older adult candidates on their anxiety.
Purpose	Prevention
Inclusion/Exclusion criteria	Inclusion criteria: Willingness to participate in the study Not having a history of mental, cardiovascular, and respiratory disorders Age 60 years and older No hearing impairment No use of sedatives and beta-blockers Not having a previous history of cataract surgery Not having severe anxiety Exclusion criteria: Unwillingness to continue participating The occurrence of events that affect the patient's anxiety
Age	From 60 years old
Gender	Both
Phase	N/A
Groups that have been masked	• Outcome assessor • Data analyser
Sample size	Target sample size: 81
Randomization (investigator's opinion)	Randomized
Randomization description	The patients will randomly assign into three groups using the balanced blocking randomization method with three permutation blocks. To do this, the letters A, B, and C were consider for the two intervention and control groups, respectively. Possible modes in the permutation block method are six modes that include (ACB, CBA, CAB, BCA, BAC, and ABC). Each mode will write on a card and the cards will assign the number one to six. Then, a mode will select by rolling of a dice, one of the six possible modes will select. Based on the selected mode, patients will allocate into three groups. This process will continue until the sample size will complete.
Blinding (investigator's opinion)	Double blinded
Blinding description	In this study, the outcome evaluator will be a person other than the main researcher who will not be aware of the study groups. The data and study groups will provide to the statistical analyst as codes.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	1 Ethics committee Name of ethics committee Ethics committee of Gonabad University of Medical Sciences Street address saadi Av , Parastar Blvd, ems department City Gonabad Province Razavi Khorasan Postal code 9691674178 Approval date 2023-11-14, 1402/08/23 Ethics committee reference number IR.GMU.REC.1402.119
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
Primary outcomes	1 Description Anxiety score in the Spiel berger questionnaire Timepoint At the beginning of the study, before the intervention, after the intervention and half an hour before the surgery Method of measurement the Spielberger questionnaire
Secondary outcomes	1 Description Breathing rate, heart rate, blood pressure Timepoint At the beginning of the study and before the intervention, after the intervention, half an hour before the operation Method of measurement Counting breathing and heart rate in one minute, mercury sphygmomanometer

Intervention groups

1

Description

For this group, the video related to the surgical procedure and operating room environment and the processes before, during and after the operation will be shown. The duration of this film is 10 minutes, which is shown individually for each patient on the day before the operation in the ophthalmologist's office.

Category

Prevention

2

Description

Intervention group: The day before the operation, the patient will visit the operating environment and the patient's inpatient department. While familiarizing the patient with the personnel and the environment, the cataract surgery process will be explained.

Category

Prevention

3

Description

Control group: The control group will go through the usual procedure of surgery and no intervention will be done.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Bohloul hospital

Full name of responsible person

Akram Nami

Street address

Saadi ave, Parastar Blvd. Bohloul Hospital

City

Gonabad

Province

Razavi Khorasan

Postal code

9691797852

Phone

+98 51 5723 6833

Email

ajam.h@gmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Hosein Ajamzibad

Street address

Vice-Chancellor of Education, Gonabad University of Medical Sciences, Saadi St., Nurse Blvd.

City

Gonabad

Province

Razavi Khorasan

Postal code

9691817818

Phone

+98 51 5722 3028

Email

moallef@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gonabad University of Medical Sciences

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

Gonabad University of Medical Sciences

Full name of responsible person

Akram Nami

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Geriatrics

Street address

Saadi ave. Parastar blvd, Bohloul Hospital

City

Gonabad

Province

Razavi Khorasan

Postal code

9691797852

Phone

+98 51 5723 6833

Email

Eoc@gmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Akram Nami

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Saadi ave. Parastar blvd, Bohlool Hospital

City

Gonabad

Province

Razavi Khorasan

Postal code

9691797852

Phone

+98 51 5723 6833

Email

Eoc@gmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Akram Nami

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Saadi ave. Parastar blvd, Bohlool Hospital

City

Gonabad

Province

Razavi Khorasan

Postal code

9691797852

Phone

+98 51 5723 6833

Email

Eoc@gmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals when publishing an article.

When the data will become available and for how long

Data access begins 3 months after publication of results

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Any data analysis will be allowed with the consent of the main researcher.

From where data/document is obtainable

The main researcher (correspondence)

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

It will be sent in the shortest time with an official request and through an email.

Comments