Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Sep 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
Bohlool hospital
Full name of responsible person
Akram Nami
Street address
Saadi ave, Parastar Blvd. Bohlool Hospital
City
Gonabad
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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
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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, Bohlool Hospital
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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

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Person responsible for updating data

Contact

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Gonabad University of Medical Sciences

Full name of responsible person
Akram Nami

Position
student

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Bachelor

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Nursery

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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