

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

" Comparison of the Impact of Cataract Surgery Preparation Training through Videos on the Elderly's Pre-operation Anxiety"

Protocol summary

Study aim

"Determining the impact of cataract surgery preparedness training through videos on the elderly's pre-operation anxiety" "Helping design non-invasive and non-pharmacological interventions to reduce the elderly's anxiety before this surgery" "Preventing post-operation complications and faster patient recovery" "Offering a new approach to national nursing interventions that would introduce this method as a non-pharmacological intervention for the elderly to the managers and nurses of the country in case of its success" "Providing accurate information regarding the operation room and the type of procedure"

Design

'A clinical trial including a control group with parallel randomized non-blinded groups of 50 patients. Randomization was conducted through permutation blocks"

Settings and conduct

"A clinical trial including a control group with parallel randomized non-blinded groups of 50 patients. Randomization was conducted through permutation blocks"

Participants/Inclusion and exclusion criteria

Patients entering this study must: "Be over 60 years old" "Understand and speak Farsi proficiently" "Be referring for their first cataract surgery" "Have gained a score of 20 or above from the evident anxiety test evaluated through the Spielberger questionnaire" "Study exclusion criteria: "Patient's withdrawal from the study and change in the surgery date or treatment plan

Intervention groups

The present study first examines patients, evident anxiety through the Spielberger questionnaire. Then, the videos will be played three times for people in the intervention group: at the clinic for the first time, one week later for the second time, and half an hour before the surgery for the last time. No particular training is delivered to those in the control group

Main outcome variables

"The primary variables of the study include the level of anxiety and training"

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201109049315N1**

Registration date: **2020-12-09, 1399/09/19**

Registration timing: **prospective**

Last update: **2020-12-09, 1399/09/19**

Update count: **0**

Registration date

2020-12-09, 1399/09/19

Registrant information

Name

Mozhgan Eftekharpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3333 5914

Email address

mozhganeftekharpour@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-19, 1399/09/29

Expected recruitment end date

2021-02-17, 1399/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
" Comparison of the Impact of Cataract Surgery Preparation Training through Videos on the Elderly's Pre-operation Anxiety"

Public title
"Comparison of the Impact of Surgery Preparation Training through Videos on Pre-operation Anxiety"

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
"Being at least 60 years old" "Patients referring for their first cataract surgery"
Exclusion criteria:
"Patient's withdrawal from the study" "Change in the surgery date or treatment plan"

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
"Permuted block randomization will be used to determine the control and intervention groups. For this purpose, 13 blocks, each made up of four parts, will be selected through sampling with replacement"

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 University of Welfare and Rehabilitation Science
Street address
Kodakyar Ave., Daneshjo Blvd.,Evin
City

Tehran
Province
Tehran
Postal code
1985713871
Approval date
2020-08-17, 1399/05/27
Ethics committee reference number
IR.USWR.REC.1399.145

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F41.9
ICD-10 code description
Anxiety disorder, unspecified

2

Description of health condition studied
Cataract
ICD-10 code
Z98.4
ICD-10 code description
Cataract extraction status

Primary outcomes

1

Description
"Anxiety score obtained from the Spielberger questionnaire"
Timepoint
"Measurement of patient anxiety at the beginning of the study(before the intervention) and half an hour before the start of surgery"
Method of measurement
"Using the Spielberger Questionnaire"

Secondary outcomes

empty

Intervention groups

1

Description
"The intervention group will be shown the film three times, the first time in the clinic, the second time next week and the third time half an hour before the operation"
Category
Prevention

2

Description

"No training is given to the control group"

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Kowsar Hospital, Semnan

Full name of responsible person

Mozhgan Eftekharpour Fatemi

Street address

Kowsar Hospital Clinic., Kashef Ave., Amin Blvd.,
Golestan Town

City

Semnan

Province

Semnan

Postal code

3519899951

Phone

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Fax

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Email

Mozhganeftekharpour@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Farahnaz Mohammadi Shahbalaghi

Street address

Kodakyar Ave., Daneshjo Blvd.,Evin

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Postal code

1985713834

Phone

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Fax

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Email

Mohammadifarahnaz@gmail.com

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Farahnaz Mohammadi Shahbalaghi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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