Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

Design, implementation, and evaluation of educational intervention through the patient decision making aid (PDA) to select correction method for patients with myopia

Protocol summary

Study aim

Evaluating the effect of educational intervention through patient decision aid (PDA) in choosing corrective laser surgery

Design

A clinical trial with a control group, with parallel groups, randomized by quadruple block method is performed on 30 patients as a control group and 30 myopic patients as a control group. Patients' knowledge and decision to choose the method of laser myopia correction is evaluated using the patient decision-making aid before and after using the guide aid. The intervention includes three phases: pre-test, content training, and post-test. Pre-test in both intervention and control groups is sent to their mobile phone in the form of an online questionnaire including evaluation of emotion, knowledge, and decision stage. The link of the website designed for the patients of the intervention group, ie the patients who are candidates for three surgical methods, will be sent and the way of working with the aid will be explained. Each person has access to educational content for 48 hours at any time and place. At the end of 48 hours, access to the educational content is automatically disabled. At the end of the tooling process, pre-test questions are asked again. During the use of the tool, the intervention group proceeds through 5 decision stages, respectively, and without passing one stage, they are not able to enter the next stage.

Settings and conduct

The study will be performed in the ophthalmologist's office in Tehran.

Participants/Inclusion and exclusion criteria

Have enough vision to browse PDA Literate Age 14 to 40 Candidate for Small Incision Lenticule Extraction, Laser-Assisted in Situ Keratomileusis, Photorefractive keratectomy

Intervention groups

Eligible patients and recipients of a PDA for corrective laser surgery.The control group does not receive educational content through PDA

Main outcome variables

Decide on the selection type of laser correction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191229045933N1**
Registration date: **2021-03-19, 1399/12/29**
Registration timing: **prospective**

Last update: **2021-03-19, 1399/12/29**
Update count: **0**

Registration date

2021-03-19, 1399/12/29

Registrant information

Name

Hanieh Delshad-Aghdam

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

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+98 21 6670 5943

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-04, 1400/01/15

Expected recruitment end date

2021-05-05, 1400/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design, implementation, and evaluation of educational intervention through the patient decision making aid (PDA) to select correction method for patients with myopia

Public title

Effect of a patient decision aid to select for myopia correction surgery method

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

All patient with enough vision for reviewing the decision aid content All Patient with enough literacy for reviewing the decision aid content All Nearsighted patient proved by ophthalmologist and optometrist Candidates for all three surgical procedures: Smile, Femto-LASIK and PRK

Exclusion criteria:

Patients have not received formal education on myopia correction

Age

From **15 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the block (quadruple) randomization method will be performed. Thus, by referring to the hospital, the researcher identifies the eligible individuals to participate in the study and divides them into two experimental and control groups by random allocation by quadruple block method. It considers the letter A for the intervention group and the letter B for the control group. Then all the permutation combinations of the letters AA and BB, which are six different combinations, and from combinations 1 to 6, one combination is randomly selected. This operation continues continuously until the sample size is reached.

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

Trabiat Modares University

Street address

Jalal Al-Ahmad St., Nasr Bridge, Tarbiat Modares University, School of Medicine

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Tehran

Province

Tehran

Postal code

111-14115

Approval date

2019-11-27, 1398/09/06

Ethics committee reference number

IR.MODARES.REC.1398.212

Health conditions studied

1

Description of health condition studied

Myopia

ICD-10 code

H52.13

ICD-10 code description

Myopia, bilateral

Primary outcomes

1

Description

Knowledge of laser correction methods for myopia

Timepoint

48 after educational intervention

Method of measurement

Through knowledge assessment questions about the three eye surgery methods listed in the patient decision aid

2

Description

The patient's decision in choosing the method of laser surgery for myopia

Timepoint

48 after educational intervention

Method of measurement

From the decision assessment questions of choosing the surgical method, contained in the patient decision aid

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention includes three phases: pre-test, content training, and post-test. The test is sent to their mobile phone in the form of an online questionnaire including assessment of feelings, knowledge and decision stage. The link of the website designed for the patients of the intervention group, i.e. the patients who are candidates for three surgical methods, will be sent and the way of working with the tool will be explained to the people. Each person has access to educational content for 48 hours at any time and place. At the end of 48 hours, access to the educational content is automatically disabled. At the end of the process of using the tool, pre-test questions are asked again.

Category

N/A

2

Description

Control group: The test is sent to their mobile phone in the form of an online questionnaire including evaluation of feelings, knowledge and decision stage. This group does not receive any training. At the end of the educational intervention, they receive a post-test questionnaire.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Farabi Eye Hospital

Full name of responsible person

Hanieh Delshad-Aghdam

Street address

Nofel Loshato St., not far from Hafez Bridge, Shahrokh Alley, No. 50, 4th floor

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Trabiat Modares University

Full name of responsible person

Yaghoub Fatollahi

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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

Trabiat Modares University

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

2

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Seyed-Farzad Mohammadi

Street address

Kargar South, Qazvin Square, Farabi Hospital, Translation Ophthalmology Research Center

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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
Tehran 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
TehranTarbiat Modares University
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Fatemeh Zarei
Position
Assistant professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Part of the data on the main consequences can be shared.
When the data will become available and for how long
Access period starts 6 months after the results are published

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

Frequent measurement analysis to evaluate the effect of education and patient decision, 6 months after the intervention

From where data/document is obtainable

By sending an email to the email address of Dr. Fatemeh Zarei f.zarei@modares.ac.ir

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

One week after sending the email by the applicant to the email address of Dr. Fatemeh Zarei f.zarei@modares.ac.ir will be answered.

Comments