

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Aug 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)

##### Phone

+98 21 6670 5943

##### Email address

hanieh.delshad@modares.ac.ir

##### 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

##### City

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

##### City

Tehran

##### Province

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##### Postal code

1131635817

##### Phone

+98 21 6670 5943

##### Email

hanieh.delshad@modares.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Trabiat Modares University

##### Full name of responsible person

Yaghoub Fatollahi

##### Street address

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

##### City

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##### Province

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##### Postal code

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##### Phone

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##### Email

hanieh.delshad@modares.ac.ir

#### 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1336616351

##### Phone

+98 21 5541 6134

##### Email

delshad.np.on@gmail.com

#### 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

**Full name of responsible person**  
Fatemeh Zarei

**Position**  
Assistant professor

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Health Promotion

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

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f.zarei@modares.ac.ir

## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
Fatemeh Zarei

**Position**  
Assistant professor

**Latest degree**  
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f.zarei@modares.ac.ir

## 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**