

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### The Effect of self-management educational program on Vision related Quality of life in Elderly with visual Impairment

#### Protocol summary

##### Summary

Overall objective: Determining the effect of self-management education program on vision related quality of life in elderly patients with visual impairment. Main intervention: Self-management educational program for people with visual impairment . First, the cognitive shortening questionnaire (AMT) for cognitive problems screening fills up for each research unit that is willing to participate in the study. In the case of obtain cognitive ability score of 7 and above, the elderly are included in the study and After completing the informed consent form by research units and obtaining demographic information by a researcher at the clinic of Khatam-ol-Anbia hospital, the elderly were enrolled and randomly assigned to two groups of intervention and control. Before the intervention, the pretest (vision related quality of life tool) was performed in both groups and then the intervention group will be subjected to self-management educational intervention . Program will be based on the educational content . After the end of the intervention and the end of the two-month follow-up, the test is performed using the vision related quality of life tool, and the score obtained from the tool is recorded in both groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017081133966N1**  
Registration date: **2017-08-16, 1396/05/25**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-08-16, 1396/05/25

#### Registrant information

##### Name

Ahmad Ghasemi

##### Name of organization / entity

Mashhad University of Medical Sciences/Khatam al anbia hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3664 0085

##### Email address

ghasemia6@mums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Mashhad University of Medical Sciences, Vice chancellor for research

#### Expected recruitment start date

2017-08-12, 1396/05/21

#### Expected recruitment end date

2017-11-12, 1396/08/21

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The Effect of self-management educational program on Vision related Quality of life in Elderly with visual Impairment

#### Public title

The Effect of self-management educational program on Vision related Quality of life in Elderly with visual Impairment

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Entry criteria include: aged 60 and above, average visual acuity, below 6.18 to 6.60 (median vision impairment classified by the World Health Organization and among the diseases including : age-related macular degeneration (AMD), glaucoma, Diabetic retinopathy), Not having acute physical and mental disorder, and cognitive impairment and having cognitive ability of 7 and above (in the cognitive impairment test for AMT), visual and auditory acuity and talking ability to the extent that they are able to participate in the research, Education at reading and writing level, residence in Mashhad Exit criteria include: Participant refusal to continue cooperation, absence of more than two sessions in the training program, and the occurrence of any physical and mental disorder during an intervention that would prevent an elderly participant in the meetings.

#### **Age**

From **60 years** old

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **60**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

self management educational program

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

##### **Street address**

International Office - Administration Center(Qoreishi Building) - Daneshgah St. - Mashhad - Iran

##### **City**

mashhad

##### **Postal code**

99191-91778

#### **Approval date**

2017-08-09, 1396/05/18

#### **Ethics committee reference number**

IR.MUMS.REC.1396.155

### **Health conditions studied**

#### **1**

#### **Description of health condition studied**

visual Impairment

#### **ICD-10 code**

H54.2

#### **ICD-10 code description**

Moderate visual impairment, binocular

### **Primary outcomes**

#### **1**

#### **Description**

Vision related Quality of life

#### **Timepoint**

pre intervention, post intervention, post followup

Duration

#### **Method of measurement**

NEI-VFQ 39

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

#### **Description**

self management educational program

#### **Category**

Lifestyle

### **Recruitment centers**

#### **1**

#### **Recruitment center**

##### **Name of recruitment center**

khatam al-anbia Eye Hospital

##### **Full name of responsible person**

Akbar Derakhshan(MD)

##### **Street address**

mashhad -shahid Gharani blvd. between Abootaleb crossroad and Ferdosi squ.- edge of shahid Gharani 41

##### **City**

mashhad

### **Sponsors / Funding sources**

#### **1**

#### **Sponsor**

##### **Name of organization / entity**

Mashhad University of Medical Sciences,Vice Chancellor for research

##### **Full name of responsible person**

Mohsen Tafaghodi

**Street address**

International Office - Administration Center(Qoreishi Building) – Daneshgah St. – Mashhad – Iran

**City**

Mashhad

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Mashhad University of Medical Sciences,Vice Chancellor for research

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Ahmad Ghasemi

**Position**

Nuesing/Graduate degree

**Other areas of specialty/work**

**Street address**

mashhad -shahid Gharani blvd. between Abootaleb crossroad and Ferdosi squ.- edge of shahid Gharani 41

**City**

Mashhad

**Postal code**

91959-65919

**Phone**

+98 51 3728 1401

**Fax**

**Email**

ghasemia6@mums.ac.ir

**Web page address**

www.mums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Hossein Karimi Monaghi

**Position**

nursing education(PH.D) and Medical Education (Masters )/Associate professor

**Other areas of specialty/work**

**Street address**

Mashhad- Doctora cross road- ebn sina Ave. Nursing and Midwifery University

**City**

Mashhad

**Postal code**

9137913199

**Phone**

+98 51 3859 1511

**Fax**

**Email**

karimih@mums.ac.ir

**Web page address**

www.mums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Ahmad Ghasemi

**Position**

Nuesing/Graduate degree

**Other areas of specialty/work**

**Street address**

mashhad -shahid Gharani blvd. between Abootaleb crossroad and Ferdosi squ.- edge of shahid Gharani 41

**City**

Mashhad

**Postal code**

**Phone**

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**Fax**

**Email**

**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*