

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

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ghasemia6@mums.ac.ir

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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

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Ahmad Ghasemi

Position

Nuesing/Graduate degree

Other areas of specialty/work

Street address

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City

Mashhad

Postal code

Phone

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Fax

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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