Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Leventhal's Model-Based Education on Treatment Adherence, Intraocular Pressure, and Visual-Related Quality of Life, in Glaucoma Patients

Protocol summary

Study aim
Effect of Leventhal model training on intraocular pressure, treatment adherence, and vision-related quality of life in glaucoma patients.

Design
A single-blind, randomized, parallel-group clinical trial will enroll 90 patients with glaucoma. Participants will be selected using a convenient method and then assigned to either an intervention or control group, with the assignment determined by color-coded cards.

Settings and conduct
Patients with glaucoma referred to Al-Zahra Ophthalmology Hospital (S) in Zahedan will be randomized 1:1 into intervention and control groups. The intervention group will receive four individual training sessions based on the Leventhal model, covering the nature, causes, symptoms, consequences, progression, and management of the disease. Social and cultural factors that influence understanding will be identified and adjusted as necessary. The control group will receive standard clinic training. A trained, blinded nurse will measure treatment adherence, vision-related quality of life, and intraocular pressure in both groups at baseline and after 8 weeks.

Participants/Inclusion and exclusion criteria
Suffering from glaucoma 18 years old Basic literacy Having a Phone for coordination Willingness to participate in the study Using medication to lower eye pressure Severe secondary visual impairment (Cataracts, Macular degeneration). Mental retardation Hearing impairment

Intervention groups
The intervention group will receive four individual training sessions based on the Leventhal model, covering disease identity, etiology, consequences, course, and management. Social and cultural factors influencing patients' understanding will also be addressed and modified as needed. The control group will receive standard clinic training.

Main outcome variables
Intraocular Pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250901067070N1**
Registration date: **2025-09-14, 1404/06/23**
Registration timing: **prospective**

Last update: **2025-09-14, 1404/06/23**
Update count: **0**

Registration date
2025-09-14, 1404/06/23

Registrant information

Name
Bibi Mahdieh Khodadadi Hosseini

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 930 202 5131

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mahdieh_kh@zbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-23, 1404/08/01

Expected recruitment end date
2026-10-23, 1405/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Leventhal's Model-Based Education on Treatment Adherence, Intraocular Pressure, and Visual-Related Quality of Life, in Glaucoma Patients

Public title

Effect of Leventhal's Model-Based Education on Glaucoma Patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Suffering from glaucoma 18 years old Basic literacy Having a Phone for coordination Willingness to participate in the study Using medication to lower eye pressure

Exclusion criteria:

Severe secondary visual impairment (Cataracts, Macular degeneration). Mental retardation Hearing impairment

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned to either the intervention or control group (1:1 ratio) by drawing colored cards from a concealed box. The box contains an equal number of cards of two different colors, each color corresponding to one of the two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

A trained nurse, blinded to patient group assignments, will measure intraocular pressure and administer treatment adherence and vision-related quality of life questionnaires.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zabol University of Medical Sciences

Street address

Educational Complex, Zabol University of Medical Sciences, Shahid Rajaee Street, Zabol, Sistan and Baluchestan, Iran

City

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Province

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Postal code

9861615881

Approval date

2025-08-11, 1404/05/20

Ethics committee reference number

IR.ZBMU.REC.1404.058

Health conditions studied

1

Description of health condition studied

Glaucoma

ICD-10 code

H40

ICD-10 code description

Glaucoma

Primary outcomes

1

Description

Intraocular pressure

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

By TOPCON KR-8900 device

Secondary outcomes

1

Description

Treatment adherence

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Treatment adherence assessment questionnaire

2

Description

Vision-related quality of life

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Vision-related quality of life assessment questionnaire

Intervention groups

1

Description

Intervention group: The intervention group will receive four individual training sessions based on the Leventhal model, covering disease identity, etiology, consequences, course, and management. Social and cultural factors influencing patients' understanding will also be addressed and modified as needed.

Category

Rehabilitation

2

Description

Control group: The control group will receive standard glaucoma education.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Ophthalmology Hospital, Zahedan

Full name of responsible person

BiBi Mahdie Khodadadi Hosseini

Street address

Al-Zahra Ophthalmology Hospital (S), Motahari Blvd., Zahedan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zabol University of Medical Sciences

Full name of responsible person

Abdolhossein Miri

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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

Zabol 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

Zabol University of Medical Sciences

Full name of responsible person

BiBi Mahdie Khodadadi Hosseini

Position

Master's student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Position
Professor

Latest degree
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Nursery

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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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All data on intraocular pressure, treatment adherence, and vision-related quality of life of patients will be collected anonymously and sent to other researchers via email upon request.

When the data will become available and for how long
Patient data can be sent after the project article is published (end of 2026).

To whom data/document is available
Academic and scientific researchers

Under which criteria data/document could be used
Data use is permitted for research and therapeutic purposes.

From where data/document is obtainable
Al-Zahra Ophthalmological Hospital (S), Motahari Blvd.,Zahedan. Bibi Mahdieh Khodadadi Hosseini mahdiekhodadadi.mk@gmail.com

What processes are involved for a request to access data/document
To access the information, please send your request to me via email. After receiving the request, I will make the necessary arrangements with the Vice President of Research and Technology at Zabol University of Medical Sciences. If there is no legal prohibition, I will send the data to you via email.

Comments