Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Nov 2026

Designing And Implementation Of The Caring Program Based On Health Expectation In Low Vision Patients With Diabetes: A Mixed Method Study

Protocol summary

Study aim
Designing a care program based on health expectation for patients with low vision due to diabetes mellitus Implementing care program based on health expectation in patients with low vision due to diabetes mellitus

Design
Clinical trial with control group with parallel groups, randomization by simple method and using patient code on 48 patients

Settings and conduct
The study site is an ophthalmology hospital. After receiving the relevant code, sampling in the center in two groups begins randomly. A care program is performed for the intervention group and for the control group of hospital routine care.

Participants/Inclusion and exclusion criteria
Having type1or2diabetes, Hospitalization Being 18 to 75 years old Existence of ocular complications due to diabetes Visual impairment and reduction with visual acuity less than 6/12 or 10/5 Absence of cognitive, psychological and other problems related to mental processes Having the ability to communicate and no hearing problems No history of diseases other than diabetes that affect vision. No history of taking drugs that affect a person's vision

Intervention groups
Care plan includes: 1. Carrying out self-care training sessions for patients with low vision due to diabetes and follow-up at home 2. Facilitate access to welfare facilities for companions and patients Facilitate access to the necessary equipment in the hospital to control vital signs and blood sugar 4. Receive nursing care based on individual needs and the request of each patient to the extent applicable 5. Observance of value-ethical principles, including correct communication with the patient, confidentiality of personal information and observance of the patient's rights 6. Introducing patients in need of financial support to the center's social worker The control group receives routine center interventions.

Main outcome variables
Patient satisfaction, self-care, general health

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220216054044N1**
Registration date: **2022-03-10, 1400/12/19**
Registration timing: **prospective**

Last update: **2022-03-10, 1400/12/19**
Update count: **0**

Registration date
2022-03-10, 1400/12/19

Registrant information

Name
Mahnaz Atapour
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 41 3385 9968
Email address
m-atapour@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-09, 1401/01/20

Expected recruitment end date
2022-06-10, 1401/03/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Designing And Implementation Of The Caring Program Based On Health Expectation In Low Vision Patients With Diabetes: A Mixed Method Study

Public title
The impact of a health care-based care program based on health expectation in low vision patients with diabetes

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
Having type 1 or 2 diabetes, which is declared by the patient himself and the patient's tests and medical record also confirm this. Hospitalization in eye surgery wards Being 18 to 75 years old Existence of ocular complications due to diabetes such as cataracts, glaucoma and retinopathy with the approval of the relevant physician and can be obtained from the patient's history from the file. Visual impairment and reduction with visual acuity less than 6/12 or 10/5 Absence of cognitive, psychological and other problems related to mental processes Having the ability to communicate and no hearing problems No history of diseases other than diabetes that affect vision. No history of taking drugs that affect a person's vision, which does not include the use of drugs that lower blood sugar.

Exclusion criteria:
Having type 1 or 2 diabetes, which is declared by the patient himself and the patient's tests and medical record also confirm this. Hospitalization in eye surgery wards Being 18 to 75 years old Existence of ocular complications due to diabetes such as cataracts, glaucoma and retinopathy with the approval of the relevant physician and can be obtained from the patient's history from the file. Visual impairment and reduction with visual acuity less than 6/12 or 10/5 Absence of cognitive, psychological and other problems related to mental processes Having the ability to communicate and no hearing problems No history of diseases other than diabetes that affect vision. No history of taking drugs that affect a person's visio

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization method and use of patient code from hospitalization file. After introducing herself and the purpose of the study, the researcher examined the individual's desire to participate in the study and obtain informed written and oral consent, selected samples from the research community as available and randomly using a patient code in one of the two The group will intervene and control. The method of randomization is such that if the patient code is even, the patient will be in the intervention group and if it is an Odd in the control group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The care plan is designed based on the health expectation of these patients and then implemented.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences

Street address
School of Nursing and Midwifery, Tehran University of Medical Sciences, Dr. Mirkhani St. (Nosrat Sharghi), Tohid Square, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
141973317

Approval date
2020-05-05, 1399/02/16

Ethics committee reference number
IR.TUMS.FNM.REC.1399.039

Health conditions studied

1

Description of health condition studied
diabetes mellitus and low vision

ICD-10 code
E08.3

ICD-10 code description
Diabetes mellitus due to underlying condition with ophthalmic complications

Primary outcomes

1

Description
Self Care using with Summary of Diabetes Self Care Activities
Timepoint
Beginning of the study, 2 weeks after the end of the intervention, 1 month after the end of the intervention
Method of measurement
Self-care of patients with low vision due to diabetes is assessed using a Summary of Diabetes Self Care Activities questionnaire. This questionnaire developed by Tobert et al. (2000) examines a person's self-care activities over the past 7 days.

2

Description
General Health with using General Health Questionnaire
Timepoint
It is evaluated at the beginning of the study and 1 month after the intervention.
Method of measurement
General Health Questionnaire. This questionnaire has four subscales of physical symptoms, anxiety, dysfunction and social function and depression, and the total score of each person is obtained from the sum of the scores of the four subscales. The General Health Questionnaire was first developed by Goldberg (1972).

Secondary outcomes

1

Description
Patient satisfaction
Timepoint
When discharging the studied samples from the hospital
Method of measurement
Patient Satisfaction Questionnaire that this questionnaire by Ameryoun et al. (2017), in two dimensions of the health sector with 21 questions and three dimensions of health and Cleaning, nursing and doctors and non-medical department with 27 questions and six dimensions of admission Staff, nutrition, welfare and facilities, religious issues and discharge were localized.

Intervention groups

1

Description
Intervention group: Receive self-care training in 4 sessions per week. They also receive nursing care based on the individual's needs in accordance with the principles of ethical values. Access to vital sign control and blood sugar control equipment is provided by the hospital to the researcher and samples, and access to hospital well-being is facilitated for the patient and his companion. In this study, patients in need of financial support are introduced to a social worker in coordination with the hospital.
Category
Treatment - Other

2

Description
Control group: Receive routine care. Routine care includes nursing care and self-care training in postoperative eye care provided by hospital nurses.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Alavi Ophthalmology Hospital, Tabriz, Iran
Full name of responsible person
Mahnaz Atapour
Street address
Alavi Hospital, 5 Mordad Squre,Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5146614596
Phone
+98 41 3266 3935
Email
m-atapour@razi.tums.ac.ir
Web page address
http://alavihospital.tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mahnaz Atapour
Street address
Headquarters of Tehran University of Medical Sciences, Corner of Ghods, Keshavarz Blvd., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3698
Fax
+98 21 6649 9713
Email
vcr@tums.ac.ir
Web page address

http://tums.ac.ir

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

Tehran University of Medical Sciences

Full name of responsible person

Mahnaz Atapour

Position

student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Unit 9, 6th floor, East Almas Tower A, behind the metro station, El Goli Square, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

516868714

Phone

+98 41 3389 1084

Email

m-atapour@razi.tums.ac.ir

Web page address

https://fnm.tums.ac.ir/

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahrzad Ghiyasvandian

Position

Faculty

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Tehran University of Medical Sciences, Dr. Mirkhani St. (Nosrat Sharghi), Tohid Square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733171

Phone

+98 21 6105 4000

Email

shghiyas@tums.ac.ir

Web page address

https://fnm.tums.ac.ir/

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahnaz Atapour

Position

student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Unit 9, 6th floor, East Almas Tower A, behind the metro station, El Goli Square, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

516868714

Phone

+98 41 3389 1084

Email

m-atapour@razi.tums.ac.ir

Web page address

https://fnm.tums.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

Yes - There is a plan to make this available

Title and more details about the data/document

Publication will be through articles and dissertations.

When the data will become available and for how long

From the end of June 1401

To whom data/document is available

University researchers

Under which criteria data/document could be used

For training and judging

From where data/document is obtainable

corresponding author

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

After receiving the request, the request will be sent to the supervisor and if she agrees, the documents will be sent.

Comments