

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of tele-nursing self-care training on anxiety and quality of life in Avestin-treated Diabetic retinopathy patients

Protocol summary

Study aim

Determining the effect of self-care education with tele-nursing approach on anxiety and quality of life in patients with diabetic retinopathy treated with Austin

Design

A clinical trial with a control group, with parallel groups, without blinding, randomized by random permutation block method, without phase and on 76 patients. www.sealedenvelope.com was used for randomization.

Settings and conduct

The researcher will go to the clinic of Khatam al-Anbia Hospital and then according to the entry criteria, she will start selecting the data and introduce the research and obtain informed consent and proceed to complete the demographic information, anxiety and quality of life questionnaire. From the time of the first meeting to the day of injection, the researcher sends the files to the intervention group via WhatsApp. On the morning of the injection, the anxiety questionnaire is completed again. From the first injection to the second injection for 4 weeks, sending educational files continues. On the morning of the second injection, the anxiety questionnaire is completed for the third time. And sending files will continue for another month. After 2 months, the quality of life and anxiety questionnaire will be completed again.

Participants/Inclusion and exclusion criteria

Inclusion criteria Diagnosis of diabetic retinopathy
Diagnosis of a candidate for Avastin
Having a smart phone
Having adequate hearing
Have a minimum literacy
No other eye diseases
No history of psychological illness
Satisfaction with participation
Infection with other diseases that lead to hospitalization
Perform surgery while studying
Non-entry criteria:
Having a history of Avastin injection

Intervention groups

For the intervention group, related trainings are sent by sending audio and video files twice a week for two

months and the control group receives routine care.

Main outcome variables

Anxiety; Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220611055134N1**

Registration date: **2022-07-12, 1401/04/21**

Registration timing: **prospective**

Last update: **2022-07-12, 1401/04/21**

Update count: **0**

Registration date

2022-07-12, 1401/04/21

Registrant information

Name

Elaheh Keshavarzian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3821 1523

Email address

keshavarziane981@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-21, 1401/04/30

Expected recruitment end date

2022-08-21, 1401/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of tele-nursing self-care training on anxiety and quality of life in Avestin-treated Diabetic retinopathy patients

Public title
The effect of tele-nursing self-care training on anxiety and quality of life in Avestin-treated patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Diagnosis of diabetic retinopathy by a doctor
 Diagnosis of a candidate for Avastin by a doctor
 Having a smart phone
 Having enough hearing
 Having a minimum literacy
 Lack of other eye diseases
 No history of psychological illness
 Satisfaction for participation
Exclusion criteria:
 Having previous experience of injecting Avastin

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is block type. To ensure an equal number of people in the study, a randomized permutation block method will be used in both groups. For this purpose, we will use the www.sealedenvelope.com website. In this way, 19 blocks of 4 members are randomly created through the site. The researcher assigns the sample to the groups. By listing the patients selected based on the inclusion criteria by the doctor, the researcher first groups the samples and then meets with the patients.

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
 Ethics committee of Mashhad University of Medical Sciences
Street address
 Ebne sina avenue-school of nursing and midwifery
City
 Mashhad
Province
 Razavi Khorasan
Postal code
 9177164383

Approval date
2022-06-07, 1401/03/17

Ethics committee reference number
IR.MUMS.NURSE.REC.1401.024

Health conditions studied

1

Description of health condition studied
Diabetic retinopathy

ICD-10 code
E08.31

ICD-10 code description
Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy

Primary outcomes

1

Description
Anxiety score in Spielberger overt and covert anxiety questionnaire

Timepoint
Anxiety will be measured before the intervention ,before the first injection , before the second injection and after the intervention.

Method of measurement
Spielberger overt and covert anxiety questionnaire

2

Description
quality of life measuring with SF36 quality of life questionnaire

Timepoint
before the intervention and two months after the quality of life of patients will be measured

Method of measurement
Sf 36 questionnaire will be used to measure the quality of life of patients

Secondary outcomes
empty

Intervention groups

1

Description

Intervention group: In the first stage of the researcher's face-to-face meeting with the patient, the researcher completes the demographic information questionnaire, quality of life questionnaires and overt and covert Spielberger questionnaire as a pre-test with the patient's help. From the time of the first appointment to the day of the Austin drug injection (one day later), the researcher sends short audio and video files of 3-4 minutes through the WhatsApp application, which includes pre-injection care and how to inject, as a personal message to The patient sends. In the morning of the injection, the anxiety questionnaire is completed for the second time. The patient is then injected by the doctor and as soon as he/she is discharged from the Austin drug injection unit, a file containing post-injection care, symptoms and complications of the injection is sent to the patient. From the day after the day of the injection until the night of the second injection for four weeks (intervals between each injection is one month) files containing how to measure and control blood sugar, importance and how to fill the blood sugar chart, importance and how to control diet, activity and Exercise is sent twice a week in a personal message (pv) and each time after receiving feedback from the patient. The night before the second injection (one month later), the files related to the injection (pre-injection care and injection method) are sent to the patient again. On the morning of the second injection (before the injection), the patient completes the anxiety questionnaire for the third time. After the injection, the patient is discharged from the Austin drug injection unit and the audio and video files continue to be sent for another month. After two months before the doctor's visit, the quality of life and anxiety questionnaire will be checked. Each time the files are sent, if a question arises for the patient, the question is first raised with the professors in the research and after receiving an answer from them, the answer is sent to the patient.

Category

Rehabilitation

2

Description

Control group: During the intervention, the control group will receive the routine care of the hospital, such as educational pamphlets available in the hospital, and after completing the study, they will receive all audio and video files and pamphlets prepared from the intervention product.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Khatam Al-Nabia Hospital in Mashhad

Full name of responsible person

Nahid Aghebati

Street address

Doctora Blvd., Mashhad School of Nursing and Midwifery

City

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Postal code

9137913199

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keshavarziane981@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nahid Aghebati

Street address

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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

Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Nahid Aghebati

Position
associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Khorasan Razavi, Mashhad, Daneshgah St., Ph.D.
Intersection, Ibn Sina St., School of Nursing and
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Email
Aghebatin@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Nahid Aghebati

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Nahid Aghebati

Position

Associate professor

Latest degree
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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

No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

The plan in this study is to publish the final report in the form of an article and a senior thesis.

When the data will become available and for how long

Probably, the results of this study will be published and made available to the public in the next two years.

To whom data/document is available

All researchers working in different institutions

Under which criteria data/document could be used

All researchers who intend to conduct meta-analysis and systematic review studies in the future can use the results of this study. Also, they can request more data in this field from researchers.

From where data/document is obtainable

Khorasan Razavi, Mashhad, Daneshgah St., Ph.D.
Intersection, Ibn Sina St., School of Nursing and
Midwifery Postal code: 9137913199 Fax: 051 38597313
Phone: 051-38591511-3 Email: nms.pr@mums.ac.ir /
aghebatin@mums.ac.ir / keshavarziane981@mums.ac.ir
Respondents: Nahid Aghebati / Elaheh Keshavarzian /
Mashhad College of Nursing and Midwifery Library

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

Request from the corresponding author using email

Comments

thanks