

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

evaluation of educational intervention based on self-care system on Tear breakup time (TBUT) in patients with dry eye .

Protocol summary

Study aim

Evaluation of the results of treatment of eye surface changes after designing and evaluating the recommended self-care system in patients with dry eye

Design

A clinical trial with a control and intervention group.superior, phase 3 on 104 patients, with a parallel group, one-way blind, www.randomization.com is used for randomization.

Settings and conduct

Patients after the initial visit and performing a clinical test that leads to the diagnosis of dry eye disease by the treating physician in the specialized ophthalmology clinic of Nourafarin. The patient is given a number that may be in the control or intervention group and then according to the group assigned to the patient, the treatment process is continued for 3 months and the results of clinical tests and questionnaires for the first week and 6 and 12 patients are taken. Correction is used at the analyst level.

Participants/Inclusion and exclusion criteria

Inclusion requirements included • Patients who have been diagnosed with dry eye based on diagnostic criteria and are over 18 years of age. • Patients who are literate, have access to a smart phone, and have the satisfaction and motivation to participate in the study and do not have mental disorders. Exclusion requirements included Simultaneity of two designs. Dissatisfaction with participating in a research project and receiving training. Patients who are unable to read and use the Internet and electronic devices due to the high severity of dry eye disease.

Intervention groups

In the intervention group, in addition to receiving the doctor's advice during the visit, a mobile application is installed on their mobile phone . In the control group, the doctor's recommendations are presented during the patient's visit.

Main outcome variables

The main outcome of the tear film evaporation test is a clinical test.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200721048162N1**

Registration date: **2020-08-31, 1399/06/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-31, 1399/06/10**

Update count: **0**

Registration date

2020-08-31, 1399/06/10

Registrant information

Name

Maryam Edalati khodabandeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3622 4876

Email address

edalati961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

evaluation of educational intervention based on self-care system on Tear breakup time (TBUT) in patients with dry eye .

Public title

evaluation of educational intervention based on self-care system on Tear breakup time (TBUT) in patients with dry eye .

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who are diagnosed with dry eye based on diagnostic criteria Patients who were satisfied and motivated to participate in the study. Patients who are at least 18 years old and do not have mental disorders. Patients who have access to and are able to use a smart phone. Patients who are literate.

Exclusion criteria:

Participate in another similar project at the same time. Dissatisfaction with participating in a research project and receiving training Patients who are unable to read and use the Internet and electronic devices due to the high severity of dry eye disease.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

Random number table using WWW.randomization.com where these numbers are placed in an envelope. The method of the envelope is that the envelopes will be prepared and printed by one of the members of the research team and random numbers with the help of Randomize.com site and will be placed inside the envelope. The lid of the envelopes will be closed and its contents will not be visible from the outside. Then, the purpose of the study is first explained to the person who meets the conditions, and the person, if he wishes, signs the informed consent form and takes an envelope, and then opens it and enters the intervention or control group based on the contents of the envelope. Allocation Concealment: Sealed envelopes

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, only the data analyst is blinded. At the end of the research, the data will be provided to them for statistical analysis.

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

No. 71, 50st St .Shahed Blvd. Ghasem Abad ., Mashhad Town

City

Mashhad

Province

Razavi Khorasan

Postal code

9186144811

Approval date

2020-03-22, 1399/01/03

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.210

Health conditions studied**1****Description of health condition studied**

dry eye

ICD-10 code

(H04.1)

ICD-10 code description

Dry Eye Syndrome

Primary outcomes**1****Description**

Tear breakup time (TBUT) is a clinical test used to assess for evaporative dry eye disease

Timepoint

It is measured at the beginning of the study (before the start of the study) and the sixth week and the 12th week after the start of using the software system.

Method of measurement

Using a Keratograph device

Secondary outcomes

1

Description

The Ocular Surface Disease Index (OSDI) .

Timepoint

It is measured at the beginning of the study (before the start of the study) and the sixth week and 12 weeks after using the software system.

Method of measurement

Short questionnaire 12 questions: The Ocular Surface Disease Index (OSDI)

Intervention groups

1

Description

"Intervention group:" After the initial visit and performing the basic dry eye tests, the training and recommendations are expressed orally by the doctor and then the designed software is installed on the patients' mobile phones and medical recommendations are sent to the patient for 3 months. During the process of using mobile software, the usual process of dry eye treatment, including the use of prescription drugs by an ophthalmologist will continue.

Category

N/A

2

Description

"Control group:" After the initial visit and performing the basic dry eye tests, the necessary training and oral recommendations are given orally by the treatment group in the first, sixth and twelfth weeks according to the routine. The follow-up period of these patients is 3 months. .

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Noorafarin Ophthalmology Clinic

Full name of responsible person

Siamak Zarei Qanavati

Street address

No.231, Mahdi Intersection, Ferdowsi Blvd, Mashhad, Iran.

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2

Recruitment center

Name of recruitment center

Bina Eye Hospital

Full name of responsible person

Alireza Esmaeili

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Seyed Razi 45., Vakilabad Blvd

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Info@EHBina.com

Web page address

http://www.ehbina.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Saeed Eslami

Street address

No. 71, 50st St .Shahed Blvd. Ghasem Abad ., Mashhad Town

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edalatim961@mums.ac.ir

Grant name

Grant code / Reference number

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

No

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

Maryam Eḏalati Khodabandeh

Position

Masters science student

Latest degree

Bachelor

Other areas of specialty/work

Medical Informatics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available