

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Effect of blinking exercise training on sign and symptoms of dry eye syndrome

#### Protocol summary

##### Study aim

The effect of blinking exercise training on the signs and symptoms of dry eye

##### Design

Clinical trial with control group, with two intervention groups and control group, double blind, randomized on 144 patients. Matlab software was used for randomization.

##### Settings and conduct

Patients were randomly selected and after obtaining informed consent, they entered the study and were placed in three groups of 48 people. The first group receives self-care training and blinking exercises, the second group receives self-care training, and the control group receives routine treatments.

##### Participants/Inclusion and exclusion criteria

Having dry eye; treated for at least 6 months; ages 15-51 years old; not using of systemic drugs with ocular complications; no failure of the lacrimal glands; no recent ocular surgery; no thyroid disorders.

##### Intervention groups

For patients in intervention group A, a training program on dry eye disease, self-care, medication use, and compliance with items that control the signs and symptoms of the disease, as well as how effective eyelid blinking is taught and performed by the facilitator. It is asked to repeat this operation several times, then its accuracy is evaluated and confirmed by the researcher. Full blinking is performed 24 times in at least 30 seconds by the intervention group A. We ask them to do this exercise every half hour during the day and wake up. In order to investigate the effect of active blinking on the signs and symptoms of dry eye, to a group of patients (group B), only trainings related to recognizing dry eye disease, self-care, and medication use (as in group A patients) by the presenter Can. There is no intervention for patients in the control group, and only the training and treatment usually performed by a doctor or nurse is controlled and recorded.

#### Main outcome variables

Signs and symptoms of dry eye

#### General information

##### Reason for update

##### Acronym

EBETSDES

##### IRCT registration information

IRCT registration number: **IRCT20200519047512N1**

Registration date: **2021-03-16, 1399/12/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-03-16, 1399/12/26**

Update count: **0**

##### Registration date

2021-03-16, 1399/12/26

##### Registrant information

##### Name

somayeh khademi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 4242 5196

##### Email address

s.khademi9511@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-03-15, 1399/12/25

##### Expected recruitment end date

2021-04-14, 1400/01/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Effect of blinking exercise training on sign and symptoms of dry eye syndrome

**Public title**  
Effect of blinking exercise training on sign and symptoms of dry eye syndrome

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Dry eye should be confirmed by the diagnosis of an ophthalmologist using clinical signs and symptoms, a schirmer test, and tear break up time. Has been treated for at least 6 months. Age 15-51 years old. Do not use systemic drugs with associated eye effects.(such as  $\beta$  - blockers Diuretics, Antihistamines, TCAs, androgens, Isotretinoin Do not have primary, secondary, or obstructive insufficiency Tear glands. Do not undergo eye surgery. Do not have thyroid disorders.  
**Exclusion criteria:**  
If do not do more than third Practice during the day (The patient is asked). Death or transfer of residence. Having any disease that requires medication, hospitalization, or surgery. Get any new eye problems.

**Age**  
From **15 years** old to **51 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**  
Target sample size: **144**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In the block method, the volume of each block must first be specified. In this study, groups can be in three states It has been replaced in the form of ABC(1), BCA(2), CBA(3), BAC(4), ACB(5), CAB(6) Which are randomly selected And are placed in 24 blocks of 6 to complete each block. All block randomization steps using From matlab software by a statistician Perform and list samples It will be given to the researcher.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Sampling, completion of pre-test questionnaires and training of groups A and B are performed by the facilitator. In order to prevent bias post-test information, post-test questionnaires are completed by a research colleague who is unaware of intervention groups A, B and control.

**Placebo**

Not used

**Assignment**  
Parallel

**Other design features**  
...

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**  
Arak University of Medical sciences

**Street address**  
Payambar Aazam (SAW) University complex, Basij Squ., Sardasht region

**City**  
Saveh

**Province**  
Markazi

**Postal code**  
3914334911

**Approval date**  
2021-02-16, 1399/11/28

**Ethics committee reference number**  
IR.ARAKMU.REC.1399.314

## 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**  
Dry eye score in the OSDI questionnaire

**Timepoint**  
Before the intervention and 7 days after the intervention

**Method of measurement**  
OSDI questionnaire

**2**

**Description**  
Dry eye rate in schirmer test and tear break up time

**Timepoint**  
Before the intervention and 7 days after the intervention

**Method of measurement**  
schirmer test

### 3

#### **Description**

Dry eye rate in tear break up time

#### **Timepoint**

Before the intervention and 7 days after the intervention

#### **Method of measurement**

Tear break up time test

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention group: For Intervention Group A patients, a training program on dry eye disease, self-care, medication use, and compliance with items that control the symptoms and signs of the disease, as well as effective eyelid blinking by the instructor taught them. They are asked to repeat this operation several times, then its accuracy is evaluated and confirmed by the researcher.

#### **Category**

Lifestyle

#### 2

#### **Description**

Intervention group: Second Intervention Group: In order to investigate the effect of active blinking on the signs and symptoms of dry eye, to a group of patients (group B), only training related to recognizing dry eye disease, self-care, and medication use (as in group A patients). ) Provided by the executor.

#### **Category**

Lifestyle

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

Modares hospital

##### **Full name of responsible person**

Somayeh Khademi

##### **Street address**

No. 1, Modarres blvd., Motahari St.,

##### **City**

Saveh

##### **Province**

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##### **Postal code**

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##### **Phone**

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##### **Email**

s.khademi9511@gmail.com

##### **Web page address**

[https://fa.irct.ir/user/trial/48474/update/recruitment\\_enter](https://fa.irct.ir/user/trial/48474/update/recruitment_enter)

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Arak University of Medical Sciences

##### **Full name of responsible person**

Dr. Ali Reza Kamali

##### **Street address**

Payambar Aazam (SAW) University complex, Basij Squ., Sardasht region

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##### **Web page address**

<https://www.arakmu.ac.ir/>

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Arak 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**

Arak University of Medical Sciences

##### **Full name of responsible person**

Kurosh Rezaie

##### **Position**

Faculty member

##### **Latest degree**

Master

##### **Other areas of specialty/work**

Nursery

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Somayeh Khademi

**Position**

Nurssing student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Person responsible for updating data**

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**Full name of responsible person**

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**Position**

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**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable