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
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Iran (Islamic Republic of)
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+98 86 4242 5196
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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 β - 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

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Web page 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
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
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Position
Faculty member
Latest degree
Master
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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