

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

The effect of vigorous physical activity on the ophthalmic symptoms of people with dry eye disease

Protocol summary

Study aim

Determining The effect of vigorous physical activity on the ophthalmic symptoms of people with dry eye disease

Design

This study is an intervention and clinical trial and will be performed without blinding. Participants are grouped into blocks. The number of samples, including the drop, is predicted to be 60 people (30 people in the intervention group and 30 people in the control group). The work process is explained to them. People who score less than or equal to 10 according to the Shermer test criteria will be identified as patients with dry eye and will be included in the study. The intervention includes strenuous physical activity in the form of: modified cognitive exercise, jumping up and down and running for 12 weeks in the university gym. Exercises will be performed under the supervision of a sports expert. Data analysis is also performed using SPSS software version 21.

Settings and conduct

Shahid Mofteh Clinic in Yasuj

Participants/Inclusion and exclusion criteria

People referring to Shahid Mofteh Clinic in Yasuj with dry eyes who want to cooperate

Intervention groups

A group of 30 people with inclusion criteria.

Main outcome variables

Dry eyes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201209049654N1**

Registration date: **2020-12-12, 1399/09/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-12, 1399/09/22**

Update count: **0**

Registration date

2020-12-12, 1399/09/22

Registrant information

Name

farkhonde bakhshi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3222 5141

Email address

fereshte.bakhshi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-09, 1399/09/19

Expected recruitment end date

2021-02-07, 1399/11/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vigorous physical activity on the ophthalmic symptoms of people with dry eye disease

Public title

The effect of vigorous physical activity on the ophthalmic symptoms of people with dry eye disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having dry eye that has been approved by an ophthalmologist and obtaining a score less than or equal to 10 in the Shermer test and obtaining a score related to moderate and severe dry eye according to the relevant table in OSDI.2- Ability to exercise 3- Willingness to participate in research 4 - No heart disease 5- No cerebrovascular disease 6- No other eye diseases such as glaucoma and eye trauma 7- No contact lenses 8- No regular and continuous exercise during the last three months

Exclusion criteria:

- Temporary blockage of lacrimal ducts by inserting silicone rods 2- Using silicone materials to temporarily or permanently block the lacrimal duct cavity to preserve tears 3- Unwillingness to continue cooperation

Age

No age limit

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be randomly assigned to block between two groups. In the block method, the researcher creates 4 blocks by considering the number of groups, which are 2 groups.

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

Research Ethics Committee of Yasouj University of Medical Sciences

Street address

Yasuj-Shahid Jalil St.-School of Nursing

City

yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591937770

Approval date

2020-07-21, 1399/04/31

Ethics committee reference number

IR.YUMS.REC.1399.100

Health conditions studied

1

Description of health condition studied

dry eye

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Dry eyes

Timepoint

Trimester

Method of measurement

OSDI questionnaire and Shermer test

Secondary outcomes

empty

Intervention groups

1

Description

A group of 30 people are eligible to enter the study who perform the intervention, ie intense sports activity (Swedish swimming, jumping and running) during a three-month period in the gym under the supervision of a sports coach. Variable changes before and after the intervention It is measured using a questionnaire and a Shermer test.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mofteh Clinic in Yasuj

Full name of responsible person

Masoud Nikbakht

Street address

Yasuj, Imam Hossein Square, next to the Faculty of Health, Shahid Mofteh Clinic

City

yasuj

Province

Kohgilouyeh-va-Boyerahmad

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7591937770

Phone
+98 74 3222 4541
Email
mdnibakht6293@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
حسین ماری اورباد
Street address
Shahid Motahari Boulevard
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Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591994799
Phone
+98 74 3334 6078
Email
oryad.hossein@yums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
mohammad latif rastian
Position
professor
Latest degree
Master
Other areas of specialty/work
Nursery
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Shahid Ghorban Ali Jalil St., School of Nursing and Midwifery
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Person responsible for updating data

Contact

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farkhonde bakhshi
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student
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Phone
+98 74 3222 4541
Email

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

Not applicable

Title and more details about the data/document

Information on the main implications of the data, including the impact of strenuous physical activity on

reducing dry eye, will be shared

When the data will become available and for how long

The data will be available after the end of the study .

To whom data/document is available

The data will be available to researchers working in universities and research institutes.

Under which criteria data/document could be used

The data is provided with the permission of the University of Medical Sciences and only the results are used for further research

From where data/document is obtainable

Mohammad Latif Rastian. Email: m.rastian@yums.ac.ir

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

The applicant must send a written request to the author of the article by e-mail and the author, after obtaining permission from Yasouj University of Medical Sciences, will provide the information to the applicant by e-mail for a maximum of 7 days.

Comments