

# 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-Boyrahmad

**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**

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**Postal code**

7591937770

**Phone**  
+98 74 3222 4541  
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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  
**City**  
yasuj  
**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  
**Street address**  
Shahid Ghorban Ali Jalil St., School of Nursing and Midwifery  
**City**

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**Province**  
Kohgilouyeh-va-Boyrahmad  
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m.rastian@yums.ac.ir

## Person responsible for scientific inquiries

#### Contact

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Professor  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Yasouj University of Medical Sciences  
**Full name of responsible person**  
farkhonde bakhshi  
**Position**  
student  
**Latest degree**  
Bachelor  
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**Province**  
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**Postal code**  
7591994799  
**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**