

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Evaluating the effects of aerobic exercise with treadmill on severity of symptoms and quality of life in female with irritable bowel syndrome with mild and moderate severity of symptoms and to compare it with female with daily usual activities

#### Protocol summary

##### Summary

It is a randomized controlled trial study that evaluate the effects of aerobic exercise with treadmill on severity of symptoms and quality of life of female with irritable bowel syndrome with mild and moderate severity of symptoms. 20 females with irritable bowel syndrome in 18-65 years old with mild and moderate severity of symptoms will enter to study. These patients will assigned to treadmill and control group. Before starting the study both of groups will fill the quality of life and severity of symptoms questionnaires. Treadmill group will exercise on treadmill 3 times a week for 6 weeks for 30 minutes. Control group will continue to same usual daily activities. At the end, the severity of symptoms and quality of life of both groups will be assessed with severity of symptoms and quality of life questionnaires.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017031927287N2**  
Registration date: **2017-04-12, 1396/01/23**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-04-12, 1396/01/23

##### Registrant information

##### Name

Javid Mostamand

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3669 3089

##### Email address

mostamand@rehab.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2017-03-20, 1395/12/30

##### Expected recruitment end date

2017-06-22, 1396/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the effects of aerobic exercise with treadmill on severity of symptoms and quality of life in female with irritable bowel syndrome with mild and moderate severity of symptoms and to compare it with female with daily usual activities

##### Public title

evaluating the effects of aerobic exercise on severity of symptoms and quality of life on female with irritable bowel syndrome

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1. female with irritable bowel syndrome with mild and moderate severity of symptoms; 2. stable

baseline blood pressure; 3. patients that are able to increase physical activity; 4. patients in 18-65 years old; 5. without cardiovascular problems. Exclusion criteria: 1. female with regular exercise program; 2. history of rheumatological diseases in lower extremity; 3. use of external device for walking; 4. history of metabolic disease, neurologic disorders, cardiovascular problems, respiratory and renal pulmonary problems that is obstructive in participation for aerobic exercise; 5. history of knee injury or surgery of knee in past recent year; 6. history of arthroplasty in joints of lower extremity; 7. history of lower extremity fracture in past 6 months; 8. evidence of clinical osteoarthritis in hip, knee, ankle and foot; 9. major vision disorders; 10. musculo skeletal, hereditary or acquired disorders in lower extremity; 11. usage of drugs that affect on metabolism or balance; 12. pregnancy; 13. organic gastrointestinal disorders.

**Age**

From **18 years** old to **65 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **20**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****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**

Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib street

**City**

Isfahan

**Postal code**

8174673461

**Approval date**

2016-09-22, 1395/07/01

**Ethics committee reference number**

IR.MUI.REC.1395.3.528

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

Irritable bowel syndrome

**ICD-10 code**

K58

**ICD-10 code description**

Irritable bowel syndrome

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

Severity of symptoms

**Timepoint**

Before and 6 weeks after intervention

**Method of measurement**

irritable bowel syndrome severity scoring system  
Questionnaire

**2****Description**

Irritable bowel syndrome quality of life

**Timepoint**

Before and 6 weeks after intervention

**Method of measurement**

irritable bowel syndrome quality of life Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Treadmill group: walking on treadmill with controlled speed in order to achieving goal heart rate for 30 minutes 3 times a week for 6 weeks

**Category**

Rehabilitation

**2****Description**

Control group: continue to same previous usual daily activities and not doing exercise activities.

**Category**

Lifestyle

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Musculo-skeletal Disorders Research Center

**Full name of responsible person**

Mozhgan Fani

**Street address**

Isfahan University of Medical Sciences

**City**

Isfahan

mozhganfani70@gmail.com;

mostamand@rehab.mui.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Javid Mostamand

**Position**

PhD

**Other areas of specialty/work****Street address**

School of Rehabilitation, Isfahan University of Medical Sciences

**City**

Isfahan

**Postal code****Phone**

+98 31 3792 5000

**Fax****Email**

mostamand@rehab.mui.ac.ir

**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Isfahan University of Medical Sciences

**Full name of responsible person**

Zahra Sadat Rezaeian

**Street address**

Isfahan University of Medical Sciences, Hezar Jerib street

**City**

Isfahan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Isfahan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Mozhgan Fani

**Position**

Bachelors degree

**Other areas of specialty/work****Street address**

Musculo skeletal Disorders Research Center, Isfahan University of Medical Sciences

**City**

Isfahan

**Postal code****Phone**

+98 31 3627 8341

**Fax****Email****Person responsible for updating data****Contact****Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Mozhgan Fani

**Position**

Bachelors degree

**Other areas of specialty/work****Street address**

School of Rehabilitation, Isfahan University of Medical Sciences

**City**

Isfahan

**Postal code****Phone**

+98 31 3627 8341

**Fax****Email**

mozhganfani70@gmail.com;

mostamand@rehab.mui.ac.ir

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*