

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

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Name of organization / entity

Isfahan University of Medical Sciences

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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

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Isfahan University of Medical Sciences, Hezar Jarib street

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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

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Person responsible for scientific inquiries

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Isfahan University of Medical Sciences
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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
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

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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