Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of low-intensity exercise bicycles with and without restriction of blood flow to strengthening the quadriceps muscles in patients with post-polio syndrome: randomized controlled trial

Protocol summary

Summary

The aim of this study is to determine the effect of low-intensity exercise bikes with and without restriction of blood flow on strengthening of the quadriceps muscle in the post-polio syndrome. Inclusion criteria: Men with the known syndrome as post-polio with records in the disabled community in Tabriz, age between 20 to 60 years, the ability to walk at least at home with or without assistive devices, the ability to pedal a stationary bicycle loaded with at least 25 watts. Exclusion criteria: having other co-morbidities, the use of steroids and sports supplementation during 3 months ago, and a regular physical activity program. Method: This study is a randomized controlled clinical trial. 60 eligible men will be selected and randomly allocated into three groups. The first intervention group will receive the stationary bicycle exercise without limitation of blood flow, the second intervention group will receive stationary bicycle exercise with limited blood flow, and control will not receive any intervention. This intervention will be lasted for 8 weeks in three groups of 20 persons. Primary outcome: Improvement some of the features of the quadriceps muscle (hypertrophy, strength, anthropometric indices and the electrical activity of muscles).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050827359N4**
Registration date: **2017-06-20, 1396/03/30**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-06-20, 1396/03/30

Registrant information

Name

Seyed Kazem Shakouri

Name of organization / entity

Tabriz University of Medical Sciences, Physical mediacine and rehabilitation department

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Recruitment status

Recruitment complete

Funding source

Physical Medicine and Rehabilitation Research Center

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2017-09-20, 1396/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of low-intensity exercise bicycles with and without restriction of blood flow to strengthening the quadriceps muscles in patients with post-polio syndrome: randomized controlled trial

Public title

The effect of bike exercise with restriction of blood flow to strengthening the quadriceps muscles in patients with

post-polio syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria Men with the known syndrome as post-polio with records in the disabled community in Tabriz; Ages between 20 to 60 years; The ability to walk at least at home, with or without assistive devices; The ability to pedal a stationary bicycle loaded with at least 25 watts; Life expectancy at least more than a year Exclusion criteria The use of psychotropic drugs or other forms of psychotherapy; Depressive men according to the Beck depression (more than 6); Having other comorbidities, according to medical examination and information in the medical records that limit interventional programs such as cardiovascular diseases, uncontrolled hypertension, seizures, uncontrolled diabetes, etc.; Failure to complete a questionnaire and carry out the necessary preliminary examination; The use of steroids and sports supplementation during 3 months ago; Having a regular physical activity program

Age

From **20 years** old to **60 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Regional Ehics Committee

Street address

Department of Research and Technology, third floor, Central Building, No. 2, Tabriz University of Medical Sciences, Golgasht, Tabriz, Iran.

City

Tabriz

Postal code

Approval date

2017-04-24, 1396/02/04

Ethics committee reference number

IR.TBZMED.REC.1396.81

Health conditions studied

1

Description of health condition studied

postpolio syndrome

ICD-10 code

G14

ICD-10 code description

Postpolio syndrome

Primary outcomes

1

Description

Muscle hypertrophy

Timepoint

First and last day of intervention

Method of measurement

Using anthropometry

2

Description

Muscle strength

Timepoint

First and last day of intervention

Method of measurement

Using isokinetic

3

Description

Range of joint motion

Timepoint

First and last day of intervention

Method of measurement

With a goniometer

4

Description

The electrical activity of muscles

Timepoint

First and last day of intervention

Method of measurement

Using EMG

Secondary outcomes

1

Description

The mean of Quality of life

Timepoint

Baseline, end of 4th week, end of 8th week

Method of measurement

Using WHO quality of life questionnaire

2

Description
GH
Timepoint
First and last day of
Method of measurement
Bloodletting

3

Description
IGF1
Timepoint
First and last day of
Method of measurement
Bloodletting

4

Description
Testosterone
Timepoint
First and last day of
Method of measurement
Bloodletting

Intervention groups

1

Description
The control group will receive no intervention and positive results, after the completion of research, will also be provided to the control group.
Category
N/A

2

Description
The first intervention group will receive resistance training without restricted blood flow. Exercises will be started with a speed of 2 km/h for 3 minutes on a stationary bike with low resistance to warm up the body and then be continued at a speed of 3 km/h for 15 minutes. The participants will be given a 60-second rest between each 5-minute exercise. After 15 minutes, pedal is pressed 2 minutes at a speed of 1 km/h to reduce the amount of muscle fatigue caused by physical activity. The intervention period will be lasted for eight weeks: three days a week on even days, 1 hour a day (from 18 to 19) in a group of 20 people that will be implemented by the attending physician.
Category
Rehabilitation

3

Description
The second intervention group will receive resistance training with restricted blood flow. Exercises will be started with a speed of 2 km/h for 3 minutes on a stationary bike with low resistance to warm up the body and then a five-centimeters tourniquet cuff is closed around the proximal of thighs for setting an obstructive pressure of 90 mm Hg pressure by barometer. Exercises will be continued at a speed of 3 km/h for 15 minutes and participants will be given a 60-second rest between each 5-minute exercise. After 15 minutes, pedal is pressed 2 minutes at a speed of 1 km/h without tourniquet cuff to reduce the amount of muscle fatigue caused by physical activity. The intervention period will be lasted for eight weeks: three days a week on odd days, 1 hour a day (from 18 to 19) in a group of 20 people that will be implemented by the attending physician.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz disabled community
Full name of responsible person
Saeid Biczadeh
Street address
City
tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor of research, Tabriz University of Medical Science
Full name of responsible person
Dr. Mohammadreza Rashidi
Street address
3rd floor, Central building number 2, Tabriz University of Medical Science , Golgasht St.
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor of research, Tabriz University of Medical Science
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

Physical Medicine and Rehabilitation group, Tabriz University of Medical Science

Full name of responsible person

Dr. seyed Kazem Shakouri

Position

Specialist in physical medicine and rehabilitation

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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