

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation the Effect of 8 Weeks Respiratory Muscle Training on Respiratory Capacity, Functional Capacity and Quality of Life on Subjects with Mild to Moderate Relapsing Remitting Multiple Sclerosis

Protocol summary

Study aim

The purpose of the present study is to examine the influence of 8 weeks of respiratory muscle training on pulmonary function and respiratory muscle strength in MS patients.

Design

A controlled clinical trial with parallel, double-blind, randomized groups on 36 patients with MS. computer-generated randomization was used for randomization.

Settings and conduct

It will be conducted on 36 patients with MS who will be referred by a neurologist at Sina Hospital. Patients are divided into two groups by computer randomization. A researcher who is not involved in any other part of the study assigns them to two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria are patients over 18 years of age, with a definitive diagnosis of relapsing-remitting MS that at least one year has passed since the diagnosis, patients are able to walk, have no relapse in a recent month, and have not received corticosteroid pulses in the last month. Exclusion criteria include patients with a history of any respiratory disease, or have an active pulmonary infection and will also be excluded from the study if they have contraindications to do aerobic activities (such as orthopedic and muscular problems), smoker, pregnancy, and participating in another research program.

Intervention groups

The intervention group will be educated exercises with a pressure threshold device (Power-breath), then patients will do exercises for 8 weeks. Patients will be followed up by telephone and the intensity of the device will be increased on a weekly basis. After 4 weeks, patients will be re-visited and side effects will be recorded. The control group will be explained only the training and importance of regular physical activity in MS patients and lifestyle modification, and both groups will be given

a booklet in this regard.

Main outcome variables

Plmax; PEmax; 6MWT; TUG test; quality of life; and spirometric parameters

General information

Reason for update

Acronym

MS

IRCT registration information

IRCT registration number: **IRCT20200827048542N1**

Registration date: **2020-10-25, 1399/08/04**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-25, 1399/08/04**

Update count: **0**

Registration date

2020-10-25, 1399/08/04

Registrant information

Name

Shima Ghannadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8863 0227

Email address

sh-ghannadi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the Effect of 8 Weeks Respiratory Muscle Training on Respiratory Capacity, Functional Capacity and Quality of Life on Subjects with Mild to Moderate Relapsing Remitting Multiple Sclerosis

Public title

Effect of Respiratory Muscle Training in Multiple Sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Definite diagnosed relapsing-remitting MS Year after diagnosed at least one year Be able to walk without support at least 10 meters Not have an relapse at least one month Taking no intravenous corticosteroid drug

Exclusion criteria:

history of any respiratory disease have an active pulmonary infection Contraindicated for aerobic activity (such as orthopedic and muscular problem) smoker pregnancy Participate in another research program

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are allocated to two groups by computer-generated randomization in blocks of 36 in a 1:1 ratio. The patients are randomized to 1 of 2 groups: the intervention group (RMT) and the control group. A research assistant not involved in any other part of the study will open the sealed opaque envelopes and assign the patients to their respective treatment groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The assessor is a sports medicine specialist who is blinded to dividing the groups of patients. Moreover, the results will also be analyzed by a statistical researcher, that is blinded to dividing the groups of patients. Teaching respiratory muscle exercises to the intervention group as well as explaining the general exercise training booklet in both groups is done by a sports medicine specialist who is not involved in patient evaluation.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

No 7, Al-e-Ahmad Highway, Tehran, IR Iran

City

Tehran

Province

Tehran

Postal code

14395-578

Approval date

2018-06-23, 1397/04/02

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1397.140

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

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

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

Maximum Inspiratory Pressure

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

Body Box machine

2**Description**

Maximum Expiratory Pressure

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

Body Box machine

Secondary outcomes

1

Description

Quality of Life

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

SF-36 questionnaire

2

Description

Aerobic capacity

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

Six Minute Walk Test (6MWT)

3

Description

Functional capacity

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

Timed Up and Go test (TUG)

4

Description

Forced Expiratory volume in the first second (FEV1)

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

Spirometry

5

Description

Forced Expiratory volume in the first second (FEV1)/Forced Vital Capacity (FVC)

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

Spirometry

6

Description

fatigue

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

Modified Fatigue Impact Scale questionnaire (MFIS)

Intervention groups

1

Description

Intervention group: They will be educated respiratory

muscle training with a pressure threshold device (Power-breath), then patients will do exercises for 8 weeks. During this time, patients will be followed up by telephone and the intensity of the device will be increased on a weekly basis.

Category

Rehabilitation

2

Description

Control group: They will be explained about the training and importance of regular physical activity in MS patients and lifestyle modification, and will be given a booklet on the subject. During the program, patients receive their usual medication as before.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Shima Ghannadi

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Web page address

<http://ni.tums.ac.ir/smrc/fa/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Abdolreza moghaddasi

Street address

Imam Khomeini Ave., Hasan Abad Sq., Sina Hospital, MS Research Center, Neuroscience Institute.

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Email

abdorrezamoghadas@gmail.com

Web page address

<http://ni.tums.ac.ir/smrc/fa/>

Grant name

Abdolreza moghaddasi

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Shima Ghannadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Sport Medicine

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Person responsible for scientific

inquiries

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Title and more details about the data/document

Specific participant data sets are to be shared (e.g., all collected deidentified IPD, IPD collected for the primary

outcome measure only, etc).

When the data will become available and for how long

starting immediately after publication

To whom data/document is available

information/documents are available for people working in academic institutions and also people working in businesses.

Under which criteria data/document could be used

For use in meta-analysis studies or systematic review articles

From where data/document is obtainable

Shima Ghannadi. Sports Medicine Research Center. No 7, Al-e-Ahmad Highway, Tehran, IR Iran. Email Address: Sh_ghannadi90@yahoo.com

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

After reviewing the email, the documents or files will be emailed to the applicant within a week.

Comments