Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

PImax; 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 interventio
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 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
Street address
No 7, Al-e-Ahmad Highway, Tehran, IR Iran
City
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Sh_ghannadi90@yahoo.com
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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Postal code

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Phone
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Email
abdorrezamoghadasi@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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No 7, Al-e-Ahmad Highway, Tehran, IR Iran

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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