

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Comparison of the effect of 8 weeks of selected TRX and aerophytic exercises on central stability function, balance and depth of sensation in patients with MS

#### Protocol summary

##### Study aim

Comparison of the effect of 8 weeks of selected exercises with TRX and Irofitance on central stability function, balance and depth of sensation in patients with MS

##### Design

Clinical trials have two experimental groups with parallel groups, one-way blind, non-random, phase 2 on 40 patients. Data analysis using SPSS software and analysis of variance with repeated measurement schemes.

##### Settings and conduct

Two experimental groups, pre-test and post-test, exercise in the gym of Isfahan MS Association. Blindness has occurred in relation to data analyzers

##### Participants/Inclusion and exclusion criteria

1- Having a person with MS according to the diagnosis of a neurologist 2- EDSS between 1 and 4 3- Female gender and not being pregnant 4- Age range between 20 and 50 5 - Not being infected with other acute or chronic disabling diseases contrary to exercise 6- Non-prohibition of a specialist doctor to perform sports exercises 7- The desire to participate and complete the form of conscious consent to participate in the study

##### Intervention groups

Intervention Group 1: TRX Group, Intervention Group 2: Aerophytic Group. In the intervention group, 1 exercise was performed using TRX band for 8 weeks and about 2 and a half months. In the intervention group, 2 exercises were performed using Traband, Dumbbell, Wood and Ball for 8 weeks and about 2 and a half months.

##### Main outcome variables

Improved central stability function; improved balance; improved sense of depth in patients with MS with EDSS less than 5; See better results of TRX Group.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200501047256N1**

Registration date: **2020-06-20, 1399/03/31**

Registration timing: **retrospective**

Last update: **2020-06-20, 1399/03/31**

Update count: **0**

##### Registration date

2020-06-20, 1399/03/31

##### Registrant information

##### Name

Fatemeh Marjani

##### Name of organization / entity

Isfahan University of Sports Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5745 3630

##### Email address

fmarjani2913@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-23, 1397/05/01

##### Expected recruitment end date

2018-08-23, 1397/06/01

##### Actual recruitment start date

2018-09-09, 1397/06/18

##### Actual recruitment end date

2018-09-16, 1397/06/25

##### Trial completion date

2018-11-26, 1397/09/05

### Scientific title

Comparison of the effect of 8 weeks of selected TRX and aerobically exercises on central stability function, balance and depth of sensation in patients with MS

### Public title

Comparison of the effect of TRX and aerobically exercises on MS patients

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

A person with MS has been diagnosed by a neurologist  
EDSS between 1 and 4  
Feminine sex and not being pregnant  
Age range between 20 and 50  
The willingness to participate and complete the form of conscious consent to participate in the study

#### Exclusion criteria:

Lack of exercise in other acute or chronic debilitating diseases  
Non-prohibition of a specialist to perform exercises  
Failure to complete pre-test research tests

### Age

From **20 years** old to **50 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

- Data analyster

### Sample size

Target sample size: **40**

Actual sample size reached: **30**

### Randomization (investigator's opinion)

Randomized

### Randomization description

In this study, using the randomization method, the block of individuals assigned to each group is almost equal and blocks are formed based on the considered variables. How to build blocks: Subjects were divided into two equal groups by choosing their favorite sport based on their ability and interest. In this research, the subjects were first given a written consent form to participate in the research. Randomization tool: Random number table was used. And by the third person in different groups, including TRX training group (person 20) and Aerofitness training group (person 20), they were placed according to the entry and exit criteria of the research and received the intervention related to the same group. There was no quasi-random and hidden method.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

According to your explanation, we did not have blindness in the subjects, and only to make our statistical analysis correct, without personal comment, statistical analysis was performed and blinding was done only in relation to statistical analysis.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Isfahan University of Sports Sciences

##### Street address

Hezar Jarib St., University of Isfahan, Central Library

##### City

Esfahan

##### Province

Isfahan

##### Postal code

8771656574

#### Approval date

2019-09-04, 1398/06/13

#### Ethics committee reference number

IR.UI.REC.1398.042

## 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

Measurement of central stability performance

#### Timepoint

Before training and 2 months after training

#### Method of measurement

Measurement of central stability function by lateral trunk tests, Sorenson and trunk flexors

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention Group 1: TRX Group. In the intervention

group, 1 exercise was performed using the TRX band for 8 weeks, 3 sessions per week, each session 1 hour for about 2 and a half months. Exercises started with stability and continued with more advanced exercises over time and during subsequent sessions. In both groups, the balance, strength and endurance of the central muscles of individuals were practiced, and finally these two intervention groups were compared with each other and the performance of individuals in both groups was examined.

**Category**

Rehabilitation

**2****Description**

Intervention Group 2: Aerofitness Group. In Intervention Group 2, the exercises were performed using Traband, dumbbells, sticks and balls for 8 weeks, 3 sessions per week, each session 1 hour for about 2 and a half months. The exercises started from beginner and stable and continued with advanced exercises. In both groups, the balance, strength and endurance of the central muscles of individuals were practiced and finally these two intervention groups were compared with each other and the performance of individuals in both groups was examined.

**Category**

Rehabilitation

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

Isfahan Province MS Association

**Full name of responsible person**

Massoud Etemadifar

**Street address**

Bahonar Street

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8154645731

**Phone**

+98 31 3273 1001

**Fax**

+98 31 3273 1080

**Email**

isfahan.salamat@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Isfahan School of Sports Sciences

**Full name of responsible person**

Nader Rahnama

**Street address**

Hezar Jarib Street

**City**

Esfahan

**Province**

Isfahan

**Postal code**

81174673441

**Phone**

+98 31 3793 2288

**Fax****Email**

moavenat-amouzeschi@dean.ui.ac.ir

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

Yes

**Title of funding source**

Isfahan School of Sports 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**

University of Esfahan

**Full name of responsible person**

Fatemeh Marjani

**Position**

coach

**Latest degree**

Master

**Other areas of specialty/work**

Rehabilitation management

**Street address**

Shahid Gharani street

**City**

Golpayegan

**Province**

Isfahan

**Postal code**

8771656574

**Phone**

+98 31 5745 3630

**Email**

f.marjani2913@gmail.com

**Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

University of Esfahan

**Full name of responsible person**

Fatemeh Marjani

**Position**

coach

**Latest degree**

Master

**Other areas of specialty/work**

Rehabilitation management

**Street address**

Shahid Qarni Street

**City**

Golpayegan

**Province**

Isfahan

**Postal code**

8771656574

**Phone**

+98 31 5745 3630

**Email**

f.marjani2913@gmail.com

## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

University of Esfahan

**Full name of responsible person**

Fatemeh Marjani

**Position**

coach

**Latest degree**

Master

**Other areas of specialty/work**

Rehabilitation management

**Street address**

Shahid Qarni Street

**City**

Golpayegan

**Province**

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8771656574

**Phone**

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f.marjani2913@gmail.com

## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available