

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Effects of 12 weeks of Resistance Exercise Training on Serum Indices in Permeability of Blood Brain Barrier Controlling, oxidative stress, Functional capacity and cognitive performance in Women with Multiple Sclerosis

#### Protocol summary

##### Study aim

The aim of the present study was to answer the question whether 12 weeks of resistance training can have an effect on serum indicators of blood-brain barrier permeability control, oxidative stress, functional and cognitive capacity of women with MS?

##### Design

The study is a randomized controlled clinical trial (RCT) with a semi-experimental design (three groups with pre- and post-testing).

##### Settings and conduct

Imam reza Hospital, Kermanshah

##### Participants/Inclusion and exclusion criteria

The inclusion criteria were as follows: a) history of at least two-year diagnosed MS; b) no relapse or acute MS exacerbation within the last six months; c) aged between 18 and 45 years; d) EDSS  $\leq$ 4; e) no other chronic diseases (metabolic, cardiovascular, renal, ...); f) no history of regular physical activity in the previous 6 months. Exclusion criteria comprised: a) severe relapses during the study period; b) participation in any extra exercise training programs; c) smoking and consuming other drugs (except MS medications); d) lack of regular attendance in the intervention; e) COVID-19 infection

##### Intervention groups

a) women with MS + non-resistance training (wwMS+non-RT) (n=15), b) women with MS + resistance training (wwMS+RT) (n=15) groups, c) fifteen age-matched healthy women as a healthy control group (HCON; n=15)

##### Main outcome variables

Indices in Permeability of Blood Brain Barrier Controlling (Matrix Metalloproteinases, tissue metalloproteinases inhibitors, S100 calcium-binding protein B)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120912010824N3**

Registration date: **2023-09-07, 1402/06/16**

Registration timing: **retrospective**

Last update: **2023-09-07, 1402/06/16**

Update count: **0**

##### Registration date

2023-09-07, 1402/06/16

##### Registrant information

##### Name

Abdolhossein Parnow

##### Name of organization / entity

Razi University of Kermanshah

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1428 3275

##### Email address

a.parnow@razi.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-07, 1400/02/17

##### Expected recruitment end date

2021-07-21, 1400/04/30

##### Actual recruitment start date

2021-05-18, 1400/02/28

##### Actual recruitment end date

2021-11-10, 1400/08/19

**Trial completion date**

2023-09-21, 1402/06/30

**Scientific title**

Effects of 12 weeks of Resistance Exercise Training on Serum Indices in Permeability of Blood Brain Barrier Controlling, oxidative stress, Functional capacity and cognitive performance in Women with Multiple Sclerosis

**Public title**

Resistance Training and Multiple Sclerosis

**Purpose**

Other

**Inclusion/Exclusion criteria****Inclusion criteria:**

history of at least two-year diagnosed RR-MS EDSS  $\leq 4$  no other chronic diseases (metabolic, cardiovascular, renal, ...) no history of regular physical activity in the previous 6 months

**Exclusion criteria:**

No contracting COVID-19

**Age**

From **18 years** old to **45 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

Actual sample size reached: **25**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

30 eligible women with relapsing-remitting MS were selected to enter the study based on inclusion/exclusion criteria. Finally, the participants were divided into two groups a) without resistance training (15 people) and b) resistance training (15 people) by simple random method and using a table of random numbers. In addition, fifteen healthy, non-athlete women aged 18-45 were selected as a healthy control group (n = 15) to monitor the current research data.

**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**

Research Working Group at the Sports Sciences Research Institute

**Street address**

Motahari Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1587958711

**Approval date**

2022-06-24, 1401/04/03

**Ethics committee reference number**

IR.SSRC.REC.1402.101

**Health conditions studied**

1

**Description of health condition studied**

Multiple Sclerosis

**ICD-10 code**

F06.8

**ICD-10 code description**

Other specified mental disorders due to known physiological condition

**Primary outcomes**

1

**Description**

Indices Related to Blood Brain Barrier Permeability (matrix metalloproteinases (MMPs) and specific tissue inhibitors of MMPs, s100B)

**Timepoint**

pre and post of exercise protocol

**Method of measurement**

blood sampling

**Secondary outcomes**

1

**Description**

Cognitive Performance

**Timepoint**

pre and post of exercise protocol

**Method of measurement**

The Brief International Cognitive Assessment for MS (BICAMS) was used to examine information processing speed and immediate verbal and visual recall. The BICAMS consists of the Symbol Digit Modalities Test (SDMT), California Verbal Learning Test-II (CVLT-II) and the Brief Visuospatial Memory Test- Revised (BVMT-R).

**Intervention groups**

## 1

### Description

Intervention group: Resistance Training, Based on the recommendations in Resistance training (RT) for pwMS, the RT program included 12 weeks, 3 sessions/week, 60-80% 1RM for 60-90 min/session. The RT program consisted of three exercises for the lower extremity (leg press, lunges, and deadlift), three exercises for the upper extremity (bench press, wide grip lat pulldown and front dumbbell raise).The training program started with a 5-minute warm-up on the ergometer bike, followed by the main exercises, and then the training program ended in each session with a 5-minute cool-down program on the ergometer bike and 5 minutes of stretching and relaxation. Also, during this period, Patients received their drug treatment supervised by specialist neurologist.

### Category

Rehabilitation

## 2

### Description

Control group: Women with MS without resistance training, These women did not participate in any exercise training during the 12 weeks of intervention and performed their normal daily activities. Also, during this period, they received their drug treatment supervised by specialist neurologist.

### Category

Other

## 3

### Description

Control group2: Healthy women without resistance training, in the same age group (18-45) were selected as a healthy control group to monitor the research data. These women did not participate in any exercise training during the 12 weeks of intervention and performed their normal daily activities.

### Category

Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Imam Reza hospital- kermanshah

#### Full name of responsible person

Nasrin Niazi Nezhad

#### Street address

Sorkhe lizheh

#### City

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#### Province

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#### Postal code

6714414874

#### Phone

+98 83 3428 3276

### Email

parnowabdolhossein@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Kermanshah University of Medical Sciences

#### Full name of responsible person

Kianoosh Khamoushian

#### Street address

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#### Email

AKHAK5678@GMAIL.COM

#### Grant name

No funded

#### Grant code / Reference number

00

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

No

#### Title of funding source

Personal

#### Proportion provided by this source

100

#### Public or private sector

Private

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Persons

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Kermanshah University of Medical Sciences

#### Full name of responsible person

Nasrin Niazi Nezhad

#### Position

PhD Student

#### Latest degree

Master

#### Other areas of specialty/work

Sport Medicine

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Abdolhossein Parnow  
**Position**  
Associate professor  
**Latest degree**  
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**Other areas of specialty/work**  
exercise physiology  
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## Person responsible for updating data

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Kermanshah University of Medical Sciences  
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**Other areas of specialty/work**

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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

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

Not applicable

### Title and more details about the data/document

No known time

### When the data will become available and for how long

No known time

### To whom data/document is available

Scientific

### Under which criteria data/document could be used

Research using

### From where data/document is obtainable

نویسنده مسؤل

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

Email

### Comments

No