

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 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 ≤ 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

Kermanshah

Province

Kermanshah

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

Sorkhe lisheh

City

Kermanshah

Province

Kermanshah

Postal code

6714414874

Phone

+98 918 830 0095

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

Street address

Razi University

City

Kermanshah

Province
Kermanshah
Postal code
6714414874
Phone
0834283276
Email
n.niazi64@gmail.com

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
Ph.D.
Other areas of specialty/work
exercise physiology
Street address
Razi university
City
Kermanshah
Province
Kermanshah
Postal code
6714414874
Phone
+98 83 3428 3276
Email
parnowabdolhossein@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Abdolhossein Parnow
Position
associate professor
Latest degree
Ph.D.
Other areas of specialty/work

exercise physiology

Street address
Razi University
City
Kermanshah
Province
Kermanshah
Postal code
6714414874
Phone
+98 83 3428 3276
Email
parnowabdolhossein@gmail.com

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