Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 ≤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 physiolgy
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 مسول
What processes are involved for a request to access data/document
Email
Comments
No