Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

The effect of twelve weeks of light aerobic exercise on cognitive and motor performances in women with non-severe Multiple Sclerosis

Protocol summary

Study aim
Determining the effect of twelve weeks of light aerobic exercise on cognitive and motor functions of women with non-severe MS

Design
Clinical trial with two experimental and control groups, without blinding; Randomized by JPower software and used on 30 patients with MS.

Settings and conduct
Exercises in the gym that are suitable for the physical conditions of MS patients, two sessions per week, and each session for one hour of light and sub-maximal aerobic exercise, for 24 sessions, under the supervision of an experienced trainer in compliance with all the conditions of these patients. will take

Participants/Inclusion and exclusion criteria
eighteen to forty years old • Female gender • The physical disability score of non-severe MS patients based on the EDSS scale is up to 5.5• Not having underlying diseases • Not taking any medicine other than the medicine needed to treat MS • Not engaging in any sports and physical therapy activities at the same time as conducting this research Exit criteria • Any dissatisfaction due to exercises • Two sessions of continuous absence or three sessions of intermittent absence Any injury to the subject due to exercises • The option to leave the test at any time, by the examinee • Criteria for not entering the research The presence of any underlying disease, including epilepsy and... • Taking certain drugs other than drugs related to MS disease

Intervention groups
After the call, qualified people will be selected and then randomly placed in two groups. Two groups will be given a pre-test, then the experimental group will be subjected to an intervention program for 12 weeks, and at the end, both groups will be given a post-test. .

Main outcome variables
Impact on the amount of dynamic balance factors; static; flexibility ; reaction time; Memory ; two-handed coordination; Fatigue rate of patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231222060493N1**
Registration date: **2024-02-10, 1402/11/21**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-10, 1402/11/21**
Update count: **0**

Registration date
2024-02-10, 1402/11/21

Registrant information

Name
marzieh mahdiabady

Name of organization / entity
Razi university of kermanshah

Country
Iran (Islamic Republic of)

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+98 83 3432 9784

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-07, 1402/11/18

Expected recruitment end date
2024-02-29, 1402/12/10

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of twelve weeks of light aerobic exercise on cognitive and motor performances in women with non-severe Multiple Sclerosis

Public title

The effect of twelve weeks of light aerobic exercise on cognitive and motor performances in women with non-severe Multiple Sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

age range of eighteen to forty years• The gender of the subjects is female.Physical disability score of non-severe MS patients based on EDSS scale up to 5.5 (30-11)• Not having underlying diseases such as chronic heart diseases, arthritis or cognitive disorders• Not taking any medicine other than the medicine needed to treat MS• Not engaging in any sports and physical therapy activities at the same time as conducting this research

Exclusion criteria:

• Any dissatisfaction or problem caused by the exercises• Two sessions of continuous absence or three sessions of intermittent absence of the subject• Any injury caused to the subject due to exercises• The option to leave the test at any time, by the examinee• Criteria for not entering the research• The presence of any underlying disease, including epilepsy and...• Taking any specific medication other than MS related medications

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee ofRazi University

Street address

Kermanshah . Taq Bostan . University St . Razy University . Deputy Research Area

City

Kermanshah

Province

Kermanshah

Postal code

6714414874

Approval date

2023-09-29, 1402/07/07

Ethics committee reference number

IR.RAZI.REC.1402.054

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Change in static equilibrium

Timepoint

Static balance is measured before interventional exercises, and this factor will be measured again after twelve weeks of interventional exercises.

Method of measurement

by STROK static balance test

2

Description

A change in dynamic equilibrium

Timepoint

Dynamic balance is measured before interventional exercises, and this factor will be measured again after twelve weeks of interventional exercises.

Method of measurement

Y balance meter device

3

Description

Change in flexibility

Timepoint

Flexibility is measured before interventional exercises, and this factor will be measured again after twelve weeks of interventional exercises.

Method of measurement
Wells flexibility test

4

Description
Change in reaction time
Timepoint
Before starting the intervention exercises, the reaction time is measured and after applying the intervention exercises for twelve weeks, this factor will be measured again.
Method of measurement
Reaction time device from Lafayette company number 6305

5

Description
Changes in bimanual coordination
Timepoint
Bimanual coordination is measured before interventional exercises, and this factor will be measured again after twelve weeks of interventional exercises.
Method of measurement
Model 32532 two-handed continuous coordination device made by Lafayette Instrument Company

6

Description
Change in memory
Timepoint
Memory is measured before interventional exercises, and this factor will be measured again after twelve weeks of interventional exercises.
Method of measurement
En-back memory evaluation software

7

Description
Change in fatigue
Timepoint
Before starting the interventional exercises, the level of fatigue is measured by the FSS fatigue questionnaire, and after twelve weeks of interventional exercises, this factor will be measured again.
Method of measurement
FSS fatigue scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: After completing all the pre-tests, the experimental group will be affected by the intervention of light and sub-maximal aerobic exercise program for twenty-four sessions in twelve weeks. The exercises will be two sessions per week, with a duration of one hour in each session, and each training session includes warming up, related exercises, and cooling down. It will be done at the end of the post-exams.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Kermanshah MS Association
Full name of responsible person
Mitra Chamani Fard
Street address
Six-story unit of two buildings, Shahid Square, Elahia Street, Kermanshah
City
Kermanshah
Province
Kermanshah
Postal code
6719945230
Email
mmehdiabady2@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Razi University of Kermanshah
Full name of responsible person
Dr. Mohammad Nabi
Street address
Faculty of sports sciences . Razy University . Taq Bostan . University St . Kermanshah . Iran
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Postal code
6714414971
Phone
+98 83 3427 4515
Email
mmehdiabady2@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Razi University of Kermanshah
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

Razi University of Kermanshah

Full name of responsible person

Marzieh Mehdi Abadi

Position

Masters Student

Latest degree

Bachelor

Other areas of specialty/work

Learning and motor control

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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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

Not applicable

Title and more details about the data/document

All data can be shared after de-identifying the subjects.

When the data will become available and for how long

Six months after the results are published

To whom data/document is available

All people if they submit an official request

Under which criteria data/document could be used

Requesting access to data for any purpose is permitted

From where data/document is obtainable

If you need to receive documents, contact Marzieh Mehdiabadi, a master's student at Razi University, via email at the following email address.mmehdiabady2@gmail.com

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

In case of submitting an official request, announcing the

relevant reasons and mentioning the full details, the data will be announced via email after 72 hours.

Comments