

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The effect of combined training (resistance - endurance) and red Grape juice supplementation on Daily Memory, Retrospective Memory, Prospective Memory and Quality of life of patients with Multiple sclerosis

Protocol summary

Study aim

Determining the effect of 8 weeks of combined training (resistance _ endurance) at home with red grape juice supplementation on daily, retrospective and prospective memory in patients with multiple sclerosis.

Design

The clinical trial with control group, with factorial groups, without blinding, simple randomized, phase zero and on 56 patients in 4 groups of practice, supplement, exercise + supplement and control with simple randomization is performed.

Settings and conduct

This research will be conducted in the field of rehabilitation and support in Kermanshah city and on women with MS aged 40-40 years. 56 patients are divided into 4 groups of exercise, supplement, exercise + supplement and control according to the expert diagnosis and without blindness. After grouping, each member of the group will find the desired questionnaires and will receive them after the answer. The groups will do the training and supplement protocol for 8 weeks and 3 sessions per week.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Multiple sclerosis, age 20 to 40 years, less than 4.5 degrees, not participating in regular exercise. Exclusion criteria: pregnancy, illness, physical weakness

Intervention groups

Exercise group: Exercise for 8 weeks and 3 times a week for 1 hour a day, exercise includes 10 minutes of warm-up, 45 minutes of the main body of the exercise and 5 minutes of cooling. Complementary group: for 8 weeks and a week Consume 250 cc of red grape juice 3 times as a snack between morning and noon. Supplement group + Exercise: Grape juice and exercise for 8 weeks and 3 times a week Control group: Perform daily activities for 8 weeks Week.

Main outcome variables

Memory, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211020052826N1**

Registration date: **2022-03-13, 1400/12/22**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-13, 1400/12/22**

Update count: **0**

Registration date

2022-03-13, 1400/12/22

Registrant information

Name

Amin Jalili sarqaleh

Name of organization / entity

Razi University of Kermanshah

Country

Iran (Islamic Republic of)

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aminjs0409@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2023-02-23, 1401/12/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of combined training (resistance - endurance) and red Grape juice supplementation on Daily Memory, Retrospective Memory, Prospective Memory and Quality of life of patients with Multiple sclerosis

Public title

The effect of exercise and grape juice on multiple sclerosis(Ms)

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with multiple sclerosis with less than ten years of history The degree of Disease is less than 4.5 Ages 20 to 40 years Not participating in regular sports activities No regular use of red grape juice one month before the study

Exclusion criteria:

Being pregnant Cardiovascular problems Inability to exercise

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

In this design, a simple targeted randomization will be used as an individual choice for each group. 4 containers will be used to place the balls and a sealed envelope will be used for the names of the individuals. An unrelated person is used for concealment and takes the names of the people out of the envelope and puts them in each of the containers. 12 people will be placed in each container and the names inside the 4 containers will be considered as research groups. Each container is considered as one of the 4 groups and each container represents one of the groups that the unrelated person puts 48 balls which includes the names of the statistical community in each container. . 12 balls are placed in each container, respectively, so that all the containers reach 12 balls, and then the names are taken out of the containers and considered as a group.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

National Committee on Ethics in Biomedical Research

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Razi University,Daneshgah St., Bostan Arch,Kermanshah.

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6714414971

Approval date

2021-01-09, 1399/10/20

Ethics committee reference number

IR.RAZI.REC.1399.073

Health conditions studied**1****Description of health condition studied**

Multiple Sclerosis (MS)

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes**1****Description**

Memory score in the Sunderland et al. Questionnaire

Timepoint

Memory is measured before the start of the study and after the end of the study (2 Munt).

Method of measurement

Sunderland Memory Questionnaire

2**Description**

Quality of life score in the World Health Organization questionnaire

Timepoint

Before the start of the study and immediately after the end of the study (2 months)

Method of measurement

World Health Organization Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The training group performs warm-ups for 10 weeks and 3 sessions per week for 10 minutes, 45 minutes of main training and 5 minutes of cooling. The exercises will be aerobic and resistance. Aerobic exercise will include 20 minutes of walking based on the individual's ability. The 45-minute resistance training will include movements such as launching forward, getting up from the chair, and folding the back of the leg. 10 minutes of warm-up training before training and 5 minutes of cooling after training.

Category

Rehabilitation

2

Description

Intervention group 2: The supplement group will consume 250 cc of red grape juice with a concentration of 68%, which is provided naturally, for 8 weeks and 3 sessions per week between morning and noon.

Category

Rehabilitation

3

Description

Intervention group 3: Exercise group + supplement for 8 weeks and 3 sessions per week will use combined exercises for 10 minutes of warm-up, 45 minutes of main training and 5 minutes of cooling with 250 cc of red grape juice with a concentration of 68%

Category

Rehabilitation

4

Description

Control group: continues its daily activities for 8 weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah MS Association Center

Full name of responsible person

Amin Jalili Sarqaleh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Razi University of Kermanshah

Full name of responsible person

Dr. Mohammad Azizi

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Grant name

Grant code / Reference number

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

No

Title of funding source

Razi University of Kermanshah

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Razi University of Kermanshah

Full name of responsible person

Amin Jalili Sarqaleh

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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