

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The effect and non- effect of physical educational program on Mental toughness, cognitive function, symptoms of related to MS (Fatigue, Paresthesia and depression) and sleeping among ill people to multiple sclerosis (MS)

Protocol summary

Summary

This study will be done with aim to determine the effect of physical educational program on Mental toughness, cognitive function, symptoms of related to MS (Fatigue, Paresthesia and depression) and sleeping among ill people to multiple sclerosis (MS) in Kermanshah. This study is a non-blinded clinical trial. The study population will consisted of all patients to MS that are referred to MS association of farabi hospital in Kermanshah that 46 persons will selected in available method and randomly will be divided into two groups (23 patients experimental group and 23 patients in control group).The experimental and control group at first study will completed the Insomnia Severity Index, Mental toughness, Fatigue, Depression, Stroop Test and Visual Analogue Scale. The experimental group in 8 weeks and in every week 3 sessions of 60 minutes and the control group will not receive any interference. After the end of 4th and 8th study, two experimental and control group will get the questioners to Insomnia Severity Index, Mental toughness, Fatigue, Depression, Stroop Test and Visual Analogue Scale and both groups will compared in these variables. After ending study, the control group will do the physical exercises in order to prevent study moral and experimental rights of abeyance. Inclusion criteria: Diagnosis of MS and willingness to participate in research, Exclusion criteria: MS relapse during interference.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062423705N4**
Registration date: **2016-06-29, 1395/04/09**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-29, 1395/04/09

Registrant information

Name

Mostafa Alikhani

Name of organization / entity

Kermanshah University of Medical Sciences -
Substance Abuse Prevention Research Center

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of
Medical Sciences

Expected recruitment start date

2016-06-22, 1395/04/02

Expected recruitment end date

2017-02-08, 1395/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect and non- effect of physical educational program on Mental toughness, cognitive function, symptoms of related to MS (Fatigue, Paresthesia and

depression) and sleeping among ill people to multiple sclerosis (MS)

Public title

The effect of physical educational program on Mental toughness, cognitive function, symptoms of related to MS and sleeping among ill people to MS

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: has no cardiovascular illnesses, epilepsy, metabolic illnesses, Orthopedic illnesses, like Knee pain, and intend to partaking in study , Exclusion criteria: the maximum one on three of the exercising sessions do not do that and MS relapse during interference.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

N/A

Randomization description**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**

Ethics committee of Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code**Approval date**

2016-05-25, 1395/03/05

Ethics committee reference number

kums.rec.1395.127

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

MS

ICD-10 code

G35

ICD-10 code description

multiple sclerosis

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

cognitive function

Timepoint

The beginning of the study (baseline), week four and end of the study (week eight)

Method of measurement

StroopTest

2**Description**

Fatigue

Timepoint

The beginning of the study (baseline), week four and end of the study (week eight)

Method of measurement

Fatigue Severity Scale (FSS)

3**Description**

Mental toughness

Timepoint

The beginning of the study (baseline), week four and end of the study (week eight)

Method of measurement

Mental toughness questionnaire (MTQ48)

4**Description**

Paresthesia

Timepoint

The beginning of the study (baseline), week four and end of the study (week eight)

Method of measurement

Visual Analogue Scale(VAS)

5**Description**

Depression

Timepoint

The beginning of the study (baseline), week four and end of the study (week eight)

Method of measurement

Beck Depression Inventory (BDI)

6

Description

sleep

Timepoint

The beginning of the study (baseline), week four and end of the study (week eight)

Method of measurement

Insomnia Severity Index (ISI)

Secondary outcomes

empty

Intervention groups

1

Description

The experimental group underwent 8 weeks, 3 sessions per week 60 minutes exercise will do

Category

Behavior

2

Description

The control group will not receive any tests

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Hospital

Full name of responsible person

Maryam Naghshbandi

Street address

Isar square, Farabi Hospital

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr.Sanobar Golshani

Position

Psychiatrist

Other areas of specialty/work

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Email

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty