

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 838264513

###### Email address

mo.alikhani@kums.ac.ir

##### 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)

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### 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

##### City

Kermanshah

#### 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

#### Street address

Isar square, Farabi Hospital

#### City

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#### Postal code

#### Phone

+98 83 3826 4513

#### Fax

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#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Full name of responsible person

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Sanobar Golshani

**Position**

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snb.gln@gmail.com

**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*