Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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
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
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Person responsible for updating data

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Full name of responsible person
Dr. Sanobar Golshani

Position
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Other areas of specialty/work

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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