

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Sep 2026

The effect and non- effect of aquatic exercise interventions on quality of sleep, mental toughness, cognitive function, fatigue, paresthesia and depression among patients with Multiple Sclerosis (MS) (Clinical trial study with control group)

Protocol summary

Study aim

This study will be done with aim to determine the effect of aquatic exercise interventions on quality of sleep, mental toughness, cognitive function, fatigue, paresthesia and depression among patients with Multiple Sclerosis (MS)

Design

Clinical trials with control group, with parallel groups, blind, randomized

Settings and conduct

Present study is a non-blinded clinical trial. The study population will consisted of all patients to MS in Kermanshah province that 70 persons will selected by available method and considering the criteria for inclusion and exclusion the study and randomly will be divided into two groups (35 patients experimental group and 35 patients in control group). Two weeks before starting the study and during the whole period of intervention, for all patients' medication treatment remains stable. The experimental group will perform an aquatic exercise in 8 weeks and in every week 3 sessions of 60 minutes and the control group will not receive any interference. Aquatic exercise will be conducted under a trained and professional instructor of aquatic exercising. Content of the sessions: warming-up, stretching, balance and coordination exercises, endurance and strengths training in the pool.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of MS: Female gender and willingness to participate in research, Exclusion criteria: MS relapse during interference

Intervention groups

The experimental group will perform an aquatic exercise in 8 weeks and in every week 3 sessions of 60 minutes that will be conducted under a trained and professional instructor of aquatic exercising and it includes a set of

warming-up, stretching, balance and coordination exercises, endurance and strengths training in the pool.

Main outcome variables

quality of sleep, mental toughness,depression, fatigue, paresthesia and neurocognitive performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150822023705N9**

Registration date: **2018-07-07, 1397/04/16**

Registration timing: **prospective**

Last update: **2018-07-07, 1397/04/16**

Update count: **0**

Registration date

2018-07-07, 1397/04/16

Registrant information

Name

Mostafa Alikhani

Name of organization / entity

Kermanshah University of Medical Sciences -
Substance Abuse Prevention Research Center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect and non- effect of aquatic exercise interventions on quality of sleep, mental toughness, cognitive function, fatigue, paresthesia and depression among patients with Multiple Sclerosis (MS) (Clinical trial study with control group)

Public title

The of aquatic exercise interventions on quality of sleep, mental toughness, cognitive function, fatigue, paresthesia and depression among patients with Multiple Sclerosis (MS)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of MS by neurologist; Female gender; Age 18-65 years; EDSS 0-6; No diagnosed cardiovascular diseases; No metabolic disorders; Psychiatric disorders and orthopedically diseases; No comorbid with other neurological diseases ; Willing and able to comply with the study conditions; Written informed consent.

Exclusion criteria:

Male gender; Unable or unwilling to adhere to the study intervention of more than 70% and MS relapse during interference

AgeFrom **18 years** old to **56 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **70****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients are divided into two equal groups (experimental and control) based on a randomized six-block table that is designed by Random allocation software. Present study is a non-blinded clinical trial

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 Blvd, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6719851115

Approval date

2018-05-22, 1397/03/01

Ethics committee reference number

kums.rec.1397.134

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

MS

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes**1****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)

2**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)

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

quality of sleep

Timepoint

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

Method of measurement

Insomnia Severity Index (ISI)

5

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)

6

Description

neurological performance

Timepoint

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

Method of measurement

StroopTest and NUCog test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The experimental group will perform an aquatic exercise in 8 weeks and in every week 3 sessions of 60 minutes that will be conducted under a trained and professional instructor of aquatic exercising and it includes a set of warming-up, stretching, balance and coordination exercises, endurance and strengths training in the pool.

Category

Behavior

2

Description

Control group: The control group will not receive any

interference

Category

N/A

Recruitment centers

1

Recruitment center**Name of recruitment center**

Farabi Hospital

Full name of responsible person

Jalal Shakeri

Street address

Isar square, Farabi Hospital

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

کوروش حمزه ای

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

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khamzehee@kums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah University of Medical Sciences

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**

Kermanshah University of Medical Sciences

Full name of responsible person

Nazanin Razazian

Position

Neurologist

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dena Sadeghibahmani

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Psychiatrics

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Person responsible for updating data**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Mostafa Alikhani

Position

Research Assistant

Latest degree

Master

Other areas of specialty/work

Psychology

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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

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

Yes - There is 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

Title and more details about the data/document

I have no plans at this time

When the data will become available and for how long

I have no plans at this time

To whom data/document is available

I have no plans at this time

Under which criteria data/document could be used

I have no plans at this time

From where data/document is obtainable

I have no plans at this time

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

I have no plans at this time

Comments