Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Age
From **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
City
Kermanshah
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6719851115
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jshakerimd@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
کوروش حمزه ای
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences Kermanshah
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Kermanshah
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Postal code
6719851115
Phone
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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
Ḏena Sadeghibahmani
Position
Researcher
Latest degree
Master
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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
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Research Assistant
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Psychology
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m.alikhani18@yahoo.com

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