Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of eight weeks of training in water on fatigue, balance and functional movement in men with multiple sclerosis

Protocol summary

Study aim
The effect of eight weeks water exercise training on fatigue, balance and motor function in men with multiple sclerosis

Design
The statistical sample was voluntarily selected from the statistical population according to the conditions of the study. Among them, 15 men with multiple sclerosis aged 18-55 years were selected by convenience sampling method. Then they were randomly divided into two groups of 8 experimental and 7 control groups.

Settings and conduct
Subjects comprise M.S.patient in Zahedan City after full testimonial,demografic informaion enrolment. EDSS for fatigue, Y balance test for balance and side jump test for functional movement will evaluate. Experimental grupe will do 8 weeks, 3 days in week woukut approximate 45 min. each sesson base on Yalfani et al (2018) and after of reserch priod will do pre test for post test.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Men between 18 and 55 years old, living in Zahedan with multiple sclerosis, Subjects should have a disability scale of 2 to 6, No limitation of exercise by the physician. Exclusion criteria: Has a history of orthopedic, cardiopulmonary disease, Have severe and sudden neurologic symptoms within 3 weeks prior to initiation of the plan, History of cardiovascular disease, History of epilepsy, History of metabolic diseases.

Intervention groups
Experimental group will do training 8 weeks in water and 3 workout in week (such as gat, high knee, squat,..etc) base on Yalfani et al (2018) without change in dosage use durg and control group during 8 weeks reserch will do normal daily active without change indosage use drug.

Main outcome variables
Fatigue, Balance, Functional movement

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200209046438N1**
Registration date: **2020-06-02, 1399/03/13**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-02, 1399/03/13**
Update count: **0**

Registration date
2020-06-02, 1399/03/13

Registrant information

Name
amirhossein jani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 54 3329 5290

Email address
amirr4182@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-20, 1399/02/01

Expected recruitment end date
2020-06-21, 1399/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of eight weeks of training in water on fatigue, balance and functional movement in men with multiple sclerosis

Public title
The effect of eight weeks of training in water on fatigue, balance and functional movement in men
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Multiple sclerosis is confirmed by a neurologist. The age range of men is 18 to 55 years. Subjects should have a disability scale of 2 to 6. No limitation of exercise by the physician No vertigo Not using walking aids
Exclusion criteria:
History of cardiopulmonary diseases Have severe and sudden neurological symptoms within 3 weeks prior to initiation of the plan History of cardiovascular disease History of epilepsy History of metabolic diseases Participation in regular exercise two months ago Mental illness History of orthopedic diseases (such as knee pain)
Age
From **18 years** old to **55 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **15**
Randomization (investigator's opinion)
Randomized
Randomization description
15 men with multiple sclerosis were selected by convenience sampling and then they werer indivisual randomly sampling with use random number table divided into two groups of 8 experimental and 7 control groups.
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 shahid Beheshti University
Street address
Daneshjo Sq. Velenjak Shahid Behesti Un.
City
Tehran
Province
Tehran
Postal code
1991745343
Approval date
2020-05-03, 1399/02/14
Ethics committee reference number
IR.SBU.REC.1399.013

Health conditions studied

1

Description of health condition studied
Multiple sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Fatigue
Timepoint
1- before the start of training period 2- Two days after the end of the training period
Method of measurement
1-Expanded Disability Status Scale (EDSS) test for evaluate fatigue

2

Description
Balance
Timepoint
1- Before the start of training period 2- Two days after the end of the training period
Method of measurement
Y balance test for evaluate balance

3

Description
Functional movement
Timepoint
1- Before the start of training period 2- Two days after the end of the training period
Method of measurement
lateral jump for evaluate functional movement

Secondary outcomes

empty

Intervention groups

1

Description
After selecting intervention group, fot 8 weeks training in water (for example: gating, knee high, squating and etc.) 3 sessone per week with Yalfani et al (2018) porotocol will do workout.
Category
Rehabilitation

2

Description
Control group: ،This group will have daily activeties routine without any inernation during reserch time (eight weeks).
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Zahedan M.S. Association
Full name of responsible person
Hamid Tabatabaei
Street address
Mahur alley 34 Alley South Misaq Tondghoyan highway Bahman sq.
City
Tehran
Province
Tehran
Postal code
1737588292
Phone
+98 21 5554 5041
Email
tabatabaei@doctor.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Hamid Tabatabaei
Street address
Mahur Alley 34 Alley South misagh Tondghouyan Highway Bahman sq.
City
Tehran
Province
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Postal code
1737588292
Phone
+98 21 5554 5041
Email
tabatabaei@doctor.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Hamid Tabatabaei
Position
assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Sport injuries and Corrective exercises
Street address
Mahur Alley 34 Alley South Misaq Tondghoyan highway Bahman sq. Physical education compus
City
Tehran
Province
Tehran
Postal code
1737588292
Phone
+98 21 5554 5041
Email
tabatabaei@doctor.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
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Email
tabatabaei@doctor.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable