

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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, demographic information enrolment. EDSS for fatigue, Y balance test for balance and side jump test for functional movement will evaluate. Experimental group will do 8 weeks, 3 days in week workout approximate 45 min. each session based on Yalfani et al (2018) and after of research period 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 gait, high knee, squat,..etc) based on Yalfani et al (2018) without change in dosage use drug and control group during 8 weeks research will do normal daily active without change in dosage 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 individual 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

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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, for 8 weeks training in water (for example: gating, knee high, squatting and etc.) 3 sessions per week with Yalfani et al (2018) protocol will do workout.

Category

Rehabilitation

2

Description

Control group: This group will have daily activities routine without any intervention during research 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.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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

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Full name of responsible person

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Position

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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