

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Effects of virtual reality training versus traditional balance training on reaction time, executive function and coordination in people with multiple sclerosis

Protocol summary

Study aim

Effects of virtual reality training versus traditional balance training on reaction time, executive function and coordination in people with multiple sclerosis

Design

A concealed, randomized, double blinded, controlled clinical trial with a parallel group design of 40 patients

Settings and conduct

Musculoskeletal Rehabilitation Research Center, School of Rehabilitation Sciences, Ahvaz Jundishapur University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: A definite diagnosis of MS, relapsing-remitting or secondary progressive types, as diagnosed by a neurologist; Ability to stand independently; Ages between 18-64 years; Ability to walk independently; Maximum score of 53 on the Berg Balance Scale; MMSE more than 24; EDSS below 5/5 Exclusion criteria: Experiencing an exacerbation of symptoms due to relapse within 3 months of the baseline measurement; Any musculoskeletal or neurological conditions except MS limiting balance or gait; Uncorrected Auditory or visual impairment; Pregnancy; Involving in the other planned treatment; Using drugs which affecting balance or gait.

Intervention groups

Control group: Perform traditional Balance exercises; Participants received 45-minute individualized (1 trainer to 1 participant) training sessions, 3 times a week for 6 weeks. Intervention group: Perform Balance exercises using Kinect; Participants received 45-minute individualized (1 trainer to 1 participant) training sessions, 3 times a week for 6 weeks.

Main outcome variables

Reaction time Executive function Coordination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171106037286N2**

Registration date: **2018-05-11, 1397/02/21**

Registration timing: **prospective**

Last update: **2018-05-11, 1397/02/21**

Update count: **0**

Registration date

2018-05-11, 1397/02/21

Registrant information

Name

Farshad Molhemi

Name of organization / entity

Musculoskeletal Rehabilitation Research Center,
Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3101

Email address

molhemi.f@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-21, 1397/02/31

Expected recruitment end date

2019-05-21, 1398/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of virtual reality training versus traditional balance training on reaction time, executive function and coordination in people with multiple sclerosis

Public title

Effect of two types of exercises on reaction speed and coordination in patients with multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: A definite diagnosis of MS, relapsing-remitting or secondary progressive types, as diagnosed by a neurologist; Ability to stand independently; Ages between 18-64 years; Ability to walk independently; Maximum score of 53 on the Berg Balance Scale; MMSE more than 24; EDSS below 5/5 Exclusion criteria: Experiencing an exacerbation of symptoms due to relapse within 3 months of the baseline measurement; Any musculoskeletal or neurological conditions except MS limiting balance or gait; Uncorrected Auditory or visual impairment; Pregnancy; Involving in the other planned treatment; Using drugs which affecting balance or gait.

Exclusion criteria:**Age**

From **18 years** old to **64 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will used in this study. Patients will be matched based on age and gender and then randomized in different groups. A statistical software will use for randomization that will be run by a person who is not a member of research team.

Blinding (investigator's opinion)

Double blinded

Blinding description

Assessments will be performed by a physical therapist who will not inform about grouping. In addition neither the patients nor the analyzer will aware of group assignment.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ahvaz Jundishapur University of Medical Science

Street address

Ground floor, Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Science

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2018-03-12, 1396/12/21

Ethics committee reference number

IR.AJUMS.REC.1396.1114

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**

Reaction time

Timepoint

Before and after intervention

Method of measurement

Force plate

2**Description**

Executive function

Timepoint

Before and after intervention

Method of measurement

Trail making test B-A

3**Description**

Coordination
Timepoint
Before and after intervention
Method of measurement
6 spot step test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Perform Balance exercises using Kinect; Participants received 45-minute individualized (1 trainer to 1 participant) training sessions, 3 times a week for 6 weeks.

Category

Rehabilitation

2

Description

Control group: Perform traditional Balance exercises; Participants received 45-minute individualized (1 trainer to 1 participant) training sessions, 3 times a week for 6 weeks. Category: rehabilitation

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Musculoskeletal Rehabilitation Research Center

Full name of responsible person

Zahra Najarzadeh

Street address

Musculoskeletal Rehabilitation Research Center,
School of Rehabilitation Sciences, Ahvaz Jundishapur
University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6135733133

Phone

+98 61 3374 3101

Email

Saeideh.monjezi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Mohamad Badavi
Street address
Ground floor, Vice Chancellor for Research and
Technology, Ahvaz Jundishapur University of Medical
Science
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3374 3101
Email
saeideh.monjezi@yahoo.com
Grant name
Grant code / Reference number
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Farshad Molhemi

Position

MSc Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

Musculoskeletal Rehabilitation Research Center,
Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6135733133

Phone

+98 61 3374 3101

Fax

+98 61 3374 3506

Email
molhemi.f@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Farshad Molhemi

Position
MSc Student of Physical Therapy

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

Street address
Musculoskeletal Rehabilitation Research Center,
School of Rehabilitation Sciences, Ahvaz Jundishapur
University of Medical Sciences

City
Ahvaz

Province
Khouzestan

Postal code
6135733133

Phone
+98 61 3374 3101

Fax

Email
f.molhemi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Farshad Molhemi

Position
MSc Student of Physical Therapy

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Musculoskeletal Rehabilitation Research Center,
School of Rehabilitation Sciences, Ahvaz Jundishapur
University of Medical Sciences

City
Ahvaz

Province
Khouzestan

Postal code
6135733133

Phone
+98 61 3374 3101

Fax

Email
f.molhemi@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is not more information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All of information will be released in the published article

When the data will become available and for how long

after publishing the article

To whom data/document is available

anyone

Under which criteria data/document could be used

for research purpose

From where data/document is obtainable

to the published article

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

email to responsible authore

Comments