

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

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

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##### 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  
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**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

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## Person responsible for scientific inquiries

### Contact

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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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**Latest degree**  
Bachelor

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**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