Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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+98 61 3374 3101

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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.Categoryrehabilitaion

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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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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