Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Combined Vibration-Stretching Exercises on Spasticity of Lower Limb Flexors and Fall Risk in Patients with Multiple Sclerosis

Protocol summary

Study aim
the effect of combined vibrational-tensile training on spasticity of lower extremity flexors and risk of multiple sclerosis.

Design
Clinical Trial with Control Group and Two Intervention Groups, 17 Patients were Selected as a Sample, and were Randomly Divided into Two Groups. The simple Randomization Method was used to Assign Individuals to two Groups that in this Method, Random Allocation Software was used to Create a Random Sequence. Then, for not Clearing that People Assigning to which Group before Allocated in other Words Allocation Concealment, was used as a Central Randomization Method.

Settings and conduct
This Research was a Quasi-experimental Study with Pre-test and Post-test Desing in Ahvaz City. 17 Patients were Selected as a Sample, and were Randomly Divided into Two Groups. Spasticity Measured by the Ashworth Modified Scale (MAS) and Fall Risk Measured by International Fall-I Risk Scale (FES-I).

Participants/Inclusion and exclusion criteria
In this study, patients with multiple sclerosis were able to walk without auxiliary tools, at least six months past their MS disease, with primary progressive MS, with no history of cardiovascular disease, epilepsy, metabolic disease, depression, anxiety, and Other psychiatric disorders, the presence of orthopedic diseases, a history of balance disorder and recurrent postural vertigo, severe pain in the lower extremity and trunk joints, vestibular disease, and visual impairment were all included with the diagnosis of a specialist physician

Intervention groups
Vibration and Combined Vibrational-Tensile Exercises

Main outcome variables
Spasticity of Lower Limb Flexors, Fall Risk

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200327046878N1**
Registration date: **2020-08-16, 1399/05/26**
Registration timing: **retrospective**

Last update: **2020-08-16, 1399/05/26**
Update count: **0**

Registration date
2020-08-16, 1399/05/26

Registrant information

Name
Ahmad Saadi

Name of organization / entity
Raja University of Qazvin

Country
Iran (Islamic Republic of)

Phone
+98 61 3337 4974

Email address
ahmadsaadi526@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-06, 1396/09/15

Expected recruitment end date
2018-03-01, 1396/12/10

Actual recruitment start date
2017-12-06, 1396/09/15

Actual recruitment end date
2018-03-01, 1396/12/10

Trial completion date
2018-07-06, 1397/04/15

Scientific title
The Effect of Combined Vibration-Stretching Exercises on Spasticity of Lower Limb Flexors and Fall Risk in Patients with Multiple Sclerosis

Public title
The Effect of Combined Vibration-Stretching Exercises Patients with Multiple Sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having MS disease with EDSS index of 2 to 4 Male gender least six months have passed since the illness Able to walk without auxiliary tools 50 to 20 years of age
Exclusion criteria:

Age
From **20 years** old to **50 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **67**
Actual sample size reached: **17**

Randomization (investigator's opinion)
Randomized

Randomization description
The simple Randomization Method was used to Assign Individuals to two Groups that in this Method, Random Allocation Software was used to Create a Random Sequence. Then, for not Clearing that People Assigning to which Group before Allocated in other Words Allocation Concealment, was used as a Central Randomization Method.

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 Sport Sciences Research Institute of Iran
Street address
Sport Sciences Research Institute of Iran
City
Tehran
Province
Tehran
Postal code
1587958711
Approval date
2020-02-16, 1398/11/27
Ethics committee reference number
IR.SSRC.REC.1399.043

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis (MS), is an autoimmune disease that affects the nervous symptom, launching an attack on its own tissue. Multiple sclerosis can range from relatively benign to somewhat disabling to devastating, as communication between the brain and oth

Primary outcomes

1

Description
spasticity of Lower limb flexors
Timepoint
Before intervention and mid-week of intervention and post-test
Method of measurement
Modified Ashworth Scale

Secondary outcomes

1

Description
Fall Risk
Timepoint
Before intervention and mid-week of intervention and post-test
Method of measurement
International Fall-I Danger Scale (FES-I)

Intervention groups

1

Description
Intervention Group 1: Vibration Exercises for 8 Weeks, 3 Sessions per Week
Category
Rehabilitation

2

Description

Intervention Group 2: Combined Vibration-Stretching Exercises for 8 Weeks, 3 Sessions per Week

Category

Rehabilitation

3

Description

Control Group: Without any Training and just doing normal Daily Activities

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Jundishapur University of Medical Sciences Faculty of Rehabilitation

Full name of responsible person

Dariush Armat

Street address

Golestan

City

Ahvaz

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Khouzestan

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6155794963

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Email

Ahmadsaadi526@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Raja University

Full name of responsible person

Hadi Miri

Street address

Novrizian, Motahhari Blvd

City

Qazvin

Province

Qazvin

Postal code

95834-34148

Phone

+98 28 3367 7101

Email

hd.miri@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Raja University

Proportion provided by this source

10

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Raja University of Qazvin

Full name of responsible person

Ahmad Saadi

Position

Masters

Latest degree

Master

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Only information about the data results available in the article can be shared
When the data will become available and for how long
When printing an article
To whom data/document is available
public
Under which criteria data/document could be used
If people have the same study or research
From where data/document is obtainable
ahmadsaadi526@gmail.com
What processes are involved for a request to access data/document
By Email: ahmadsaadi526@gmail.com and the Reason for Using the Documents
Comments