Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the effects of Cooksey - Cawthorne and Frenkel exercises on balance and fatigue dimensions in patients with multiple sclerosis

Protocol summary

Summary

Objective: Comparison the effects of Cooksey - Cawthorne and Frenkel exercises on balance and fatigue dimensions in patients with multiple sclerosis. The study population: consist of multiple sclerosis patients who have had recorded accounts in Vice-Chancellor in treatment affairs of Yasuj University of Medical Sciences. Inclusion and exclusion criteria: Inclusion criteria include diagnosis of multiple sclerosis by a physician; receive mark 21-40 in berg balance scale and receive mark 54-106 in fatigue impact scale; having at least literacy and having at least conditions for participate to study. Exclusion criteria included relapses during the intervention. Sample size: 25 patients in Cooksey-Cawthorne exercise group (group 1), 25 patients in Frenkel exercise group (Group 2) and 25 patients in control groups (Group 3) were allocated. In Group 1 Cooksey-Cawthorne exercise program presented as a group to research units and they will be asked during an 3-months, three times a week and 45 minutes per session to do exercise that includes eye and head movements in sitting position which must be done at first slowly and then faster; movements of the head and trunk in sitting position and standing exercises. In Group 2, Frenkel exercise program presented as a group to research units and they will be asked during an 3-months, three times a week and 45 minutes per session to do exercise in a state of supine, sitting and standing. In Group 3, control group receive no specific intervention. Primary outcomes: body balance, fatigue dimensions and fatigue severity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031527063N1**
Registration date: **2016-05-12, 1395/02/23**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-05-12, 1395/02/23

Registrant information

Name
Fatemeh Karami
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Yasuj Univercity of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Yasuj University of Medical Sciences

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-06-04, 1395/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of Cooksey - Cawthorne and Frenkel exercises on balance and fatigue dimensions in patients with multiple sclerosis

Public title

Effects of rehabilitation interventions on balance and fatigue in MS patients

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: diagnosis of multiple sclerosis by a physician, at least in the last 6 months; being patient in remission period; ability to stand without assistance for 30 seconds and walk without help an area of 6 m; receive mark 21-40 in berg balance scale; receive mark less than 5/5 in degree of disability and diagnosis by doctor; receive informed consent of patient and if necessary legal guardian; patient willingness to participate in the study; no participate in the same study; not doing sports activities in the last 6 months; no risk of acute or chronic disease other than multiple sclerosis and receive mark 54-106 in fatigue impact scale. Exclusion criteria: lack of patient motivation to continue working; relapses during the intervention; having tired too so that the patient is not able to do the exercises; migration and death.
Age
From **15 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Seventy-five patients with multiple sclerosis by blocking will be divided into three groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Yasuj University of Medical Sciences
Street address
Research Management of Yasuj University of Medical Sciences, Research and Technology Deputy of Yasuj University of Medical Sciences, Shahid Motahary Blvd., Yasuj, Iran
City
Yasuj
Postal code
Approval date
2016-03-14, 1394/12/24
Ethics committee reference number
IR.YUMS.REC.1394.180

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
Body balance
Timepoint
Before the intervention, a month and a half after the intervention and after intervention
Method of measurement
Berg balance scale

2

Description
Fatigue Dimensions
Timepoint
Before the intervention, a month and a half after the intervention and after intervention
Method of measurement
Fatigue Impact Scale

3

Description
Fatigue Severity
Timepoint
Before the intervention, a month and a half after the intervention and after intervention
Method of measurement
Exclusive Fatigue Severity Scale for multiple sclerosis patients

Secondary outcomes

empty

Intervention groups

1

Description
In Group 1 Cooksey-Cawthorne exercise program presented as a group to research units and they will be asked during an 3-months, three times a week and 45

minutes per session to do exercise that includes eye and head movements in sitting position which must be done at first slowly and then faster; movements of the head and trunk in sitting position and standing exercises.

Category

Rehabilitation

2

Description

In Group 2, Frenkel exercise program presented as a group to research units and they will be asked during an 3-months, three times a week and 45 minutes per session to do exercise in a state of supine, sitting and standing.

Category

Rehabilitation

3

Description

In Group 3, control group receive no specific intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Office of an assisstant of treatment of Yasuj University of Medical Science

Full name of responsible person

Dr Ardashir Afrasiabifar

Street address

Nursing and Midwifery College, Shahid Dr. Jalil St., Yasuj, Iran

City

Yasuj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Yasuj University of Medical Sciences

Full name of responsible person

Dr. Mehdi Akbartabar Tori

Street address

Research Management of Yasuj University of Medical Sciences, Research and Technology Deputy of Yasuj University of Medical Sciences, Shahid Motahary Blvd., Yasuj, Iran

City

Yasuj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Yasuj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Dr Ardeshir Afrasiabifar

Position

Ph.D of Medical Surgical Nursing- Associate Professor

Other areas of specialty/work

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Full name of responsible person

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty