Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of a Combined Intervention program on objective and subjective measures related to balance and walking, quality of life, and stress in people with multiple sclerosis

Protocol summary

Study aim
Check out The Effect of a Combined Intervention program on objective and subjective measures related to balance and walking, quality of life, and stress in people with multiple sclerosis

Design
Clinical trial with randomized, Not blind, experimental and control groups

Settings and conduct
Exercises are held three sessions a week at the MS Society of Arak and at the beginning and end of the study, pre-test and post-test will be taken from the subjects

Participants/Inclusion and exclusion criteria
1. Selection of persons with a score of 2 to 4 scale, as the physical disability scale of the subjects group 2. The age range of subjects was 20-60 years 3. If they have a disease, other than multiple sclerosis, they are removed from the study

Intervention groups
One group performs cognitive and motor training and one group does not exercise as a control group

Main outcome variables
Gait speed, balance, quality of life, stress, Trust in balance, fear of falling,

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190715044226N1**
Registration date: **2019-12-25, 1398/10/04**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-25, 1398/10/04**
Update count: **0**

Registration date
2019-12-25, 1398/10/04

Registrant information
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-10, 1398/09/19

Expected recruitment end date
2020-01-09, 1398/10/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of a Combined Intervention program on objective and subjective measures related to balance and walking, quality of life, and stress in people with multiple sclerosis

Public title
The Effect of a Cognitive-motor program on balance and gait, quality of life, and stress management in patients with multiple sclerosis

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Selection of persons with a score of 2 to 4 scale, as the physical disability scale of the subjects group The age range of subjects was 20-60 years Patients except multiple sclerosis were not affected by another diseas Patients had the ability to participate in all training sessions Patients were good sampling of society with multiple sclerosis
Exclusion criteria:
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization with purposeful randomization unit
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The study groups included a group that is receiving the intervention and group without intervention

Secondary Ids

1

Registry name
Secondary trial Id
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Arak University of Medical Sciences
Street address
Pardis site of University Medical Science., Deputy of research., Basij Square., Arak
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Markazi
Postal code
3848176941
Approval date
2019-08-03, 1398/05/12
Ethics committee reference number
IR.ARAKMU.REC.1398.134

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
Static balance
Timepoint
One day before the start of the Static balance training protocol is assessed and participants are performed for 6 weeks, three sessions a week, and 48 hours after the last day of training, re-Static balance will be assessed.
Method of measurement
One-leg balance

2

Description
Speed walking
Timepoint
One day before the start of the Speed walking training protocol is assessed and participants are performed for 6 weeks, three sessions a week, and 48 hours after the last day of training, re-Speed walking will be assessed.
Method of measurement
Timed 25-Foot Walk

3

Description
Quality of life
Timepoint
One day before the start of the quality of life training protocol is assessed and participants are performed for 6 weeks, three sessions a week, and 48 hours after the last day of training, re-quality of life will be assessed.
Method of measurement
Multiple Sclerosis Impact Scale (MSIS-29)

4

Description
stress
Timepoint
One day before the start of the stress training protocol is

assessed and participants are performed for 6 weeks, three sessions a week, and 48 hours after the last day of training, re-stress will be assessed.

Method of measurement

Stress Scale-DASS-21

5

Description

Dynamic balance

Timepoint

One day before the start of the Dynamic balance training protocol is assessed and participants are performed for 6 weeks, three sessions a week, and 48 hours after the last day of training, re-Dynamic balance will be assessed.

Method of measurement

Timed Up and Go Test

6

Description

Fear of falling

Timepoint

One day before the start of the Fear of falling training protocol is assessed and participants are performed for 6 weeks, three sessions a week, and 48 hours after the last day of training, re-Fear of falling will be assessed.

Method of measurement

Short scale "Falling efficiency" international form in multiple sclerosis patients

7

Description

Trust balance

Timepoint

One day before the start of the Trust balance training protocol is assessed and participants are performed for 6 weeks, three sessions a week, and 48 hours after the last day of training, re-Trust balance will be assessed.

Method of measurement

Scale of trust in the special balance of activities

Secondary outcomes

empty

Intervention groups

1

Description

The participation group: The testing group will do the balancing exercises for 6 week and 45 minutes a session. The training plan includes the following: 5 warmup sessions(5 minutes), initial stretch(5 minutes), strength exercises for lower body(15 minutes), balancing exercises(15minutes) and cooling down(5 minutes), all of these will be done under the close supervition of a coach in a standard gym. The 5 minute-warmup includes walking, The 5 minute-initial stretch, flat arms stretch, upper head stretch, triceps stretch, shoulder stretch, quadriceps femoris stretch, Hamestring stretch while grounded(sitting down), strength training for lower body for 15 minutes, Hamstring flexion, crus extension, knee lifting, thighbone abduction and adoction, leaning and opening the ankle, ankle whirl, (Bottom squeeze) scot with a chair, scot with the wall, pulling up the legs from the sides, balancing exercises for 15 minutes, balancing with one leg, up-right sitting on a ball, dynamic sitting on a ball, turning to the sides, leaning the hands to the sides from up the head, The last stretch(cool down) 5 minutes. These exercises all exist in the initial stretches. To control the stress in this experiment, stress management will be done cognitive-behavioral style, during 10 sessions of 60 minutes and in groups. Sessions will start with relaxation trainings which include practicing relaxation techniques, in the second port of every session cognitive-behavioral techniques are taught combined with issues related to patients health. Every session includes the following details: First session: in troduction, introducing the plans, getting to know the stress-makers, and stress reactions, muscular relaxation training for 16 muscle groups. Second session: gradual muscle relaxation training for 8 muscle groups and knowing how stress affects thoughts, feelings and behavior. Third session: breathing exercise, visualization, and mutual analysis of thoughts and feelings and in active gradual muscular relaxation and the introduction of some common negative thoughts and cognitive deviations. Fifth session:Training self-born weight and heat, and illogical thought replace ment with logical thoughts. Sixth session: self-born training for heart beat, abdominal and for head breath, training different practical reaction styles. Seventh session: self-born training along with visualization and self-telling and using effective check responses. Eighth session: practicing mantra meditation and training anger management techniques. Nineth session: meditation and breath count training and training expressions in interpersonal relationships. Tenth session: descriping the benefits of social support, measuring the social support domain, perceiving it´s maintenance drawbacks and training social support techniques and planning personal stress management.

Category

Lifestyle

2

Description

Control group: The control group pre-test will be taken at the same time as the test group. During the 6 weeks of the test group doing the training protocol, the control group has no exercise or training and continues the ordinary life and again after this time, they will have their post-test with the test group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
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2

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3

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Sponsors / Funding sources

1

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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
The University of Arak
Proportion provided by this source
1
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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable