Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effectivness of the Eight Week of Functional Exercises with the Approach of Ultimate fit on the Parameters of Balance Muscle Strengths, Fatigue, Gait and Activity of Daily Living of Women with Multiple sclerosis.

Protocol summary

Study aim

Investigating the effectiveness of functional exercises with the ultimate fit approach on the parameters of balance, muscle strength, gait, walking and activity of daily living in women with multiple sclerosis.

Design

The clinical trial has two experimental and control groups. Randomization is done with the help of randomization software by someone outside the research team, and the person who performs the analyzes is not aware of the group allocation. Due to the nature of the intervention, blinding is not possible for patients and therapists

Settings and conduct

The subjects will be divided into two control and experimental groups. The experimental group will perform functional exercises with the altimate fit approach in Kashani Hospital, Isfahan. The exercises of this research are similar to the daily activities of a person's life, which are difficult to perform, and will be performed aerobically and strength-wise. These exercises are graded

Participants/Inclusion and exclusion criteria

not being pregnant, not suffering from osteoporosis, joint pains and knee arthritis that lead to the inability to perform exercises, not suffering from cardiovascular disease, blood pressure and mental diseases, at least one month has passed since the last date Recurrence of the disease, non-use of drugs, alcohol and psychoactive pills and voluntary willingness to participate in the research

Intervention groups

The participants will be divided into two intervention and experimental groups. The experimental group will perform functional exercises with the maximum preparation approach, and the control group will receive common treatments for patients with multiple sclerosis that they want.

Main outcome variables

Increasing balance in multiple sclerosis patients, reducing fatigue, increasing muscle strength, improving walking parameters, improving the ability to perform daily life activities

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221207056740N1**
Registration date: **2023-02-12, 1401/11/23**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-12, 1401/11/23**
Update count: **0**

Registration date

2023-02-12, 1401/11/23

Registrant information

Name

Marzie Saffari

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-01-30, 1401/11/10
Expected recruitment end date
2023-03-30, 1402/01/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effectivness of the Eight Week of Functional Exercises with the Approach of Ultimate fit on the Parameters of Balance Muscle Strengths, Fatigue, Gait and Activity of Daily Living of Women with Multiple sclerosis.

Public title
The Effectivness of Functional Exercises with the Approach of Ultimate fit on the Parameters of Balance Muscle Strengths, Fatigue, Gait and Activity of Daily Living of Women with Multiple sclerosis.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
being female having the age of 30 to 40 Taking informed consent from the subjects to participate in research
Exclusion criteria:
being pregnant have osteoarthritis ,joint pain and knee arthritis that lead to inability in doing exer6 have cardiovascular diseases,blood pressure and scycological disorder elapsing less than one month from the last relapse using the narcotics drugs ,alcohol and Psychedelic pills
Age
From **30 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
First, we will select 24 people from among the files of patients with MS referred to Dr. Vahid Shaygan Nejad in Kashani Hospital in Isfahan, and if they meet the inclusion criteria, they will be included in the study, then they will be randomly assigned to experimental and control groups. The help of the randomization software is done by someone outside the research team, and the person who performs the analyzes is not aware of the allocation of the groups. The said software was designed by Mahmoud Soqaei. By entering the software, it is enough to specify the number of groups and the required sample size, and the software randomly allocates the sample size to 2 groups. The specified numbers will be assigned to the people who are selected
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 Islamic Azad University of Isfahan, Khorasgan
Street address
East J St., Arghvanieh, University Blvd
City
Esfahan
Province
Isfehan
Postal code
8155139991
Approval date
2022-11-08, 1401/08/17
Ethics committee reference number
IR.IAU.KHUISF.REC.1401.260

Health conditions studied

1

Description of health condition studied
Multiple sclerosis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Balance improvement rate
Timepoint
The beginning of the study and the end of the study
Method of measurement
berg balance questionnaire and posturography device

2

Description
Fatigue reduction rate
Timepoint
The beginning of the intervention and the end of the intervention

Method of measurement
Fatigue Severity Scale

3

Description
Muscle strength
Timepoint
The beginning of the study and the end of the study
Method of measurement
Dynamometer device

Secondary outcomes

1

Description
The amount of independence in activity of daily living
Timepoint
The beginning of the study and the end of the study
Method of measurement
Bartel's Basic Activities of Daily Life Questionnaire will be used to measure the level of participation of a person in daily life activities.

2

Description
gait parameters
Timepoint
The beginning of the study and the end of the study
Method of measurement
3D gait analysis device

Intervention groups

1

Description
The experimental group will perform functional exercises for eight weeks with the maximum preparation approach. The maximum preparation approach means an approach in which the exercises are performed in combination and a training session does not focus on improving a specific factor, for example in one session Exercises are not only strength or aerobic exercises or exercises that affect balance, but a combination of aerobic strength and balance exercises are performed simultaneously in a training session. Also, in this training program, the intensity of the exercises is determined specifically according to the conditions of the audience. Each training session will be divided into three parts: warm-up, aerobic exercises and strength exercises.The Borg index will be used to grade the intensity of aerobic exercises, and the subject will first perform the average level of the Borg index. Indicators of the average level of aerobic exercises (score 11 to 13 of the Borg index): At the average level of the Borg index, the heart rate is 40 to 60% of the maximum heart rate of the person. A person in this state can speak but cannot sing. For this reason, we determine the target heart rate range for exercises for each subject using Caronen's formula.The duration of aerobic exercises is considered to be at least 10 minutes, and as the person's ability improves, the time of aerobic exercises gradually increases and reaches 30 minutes.A number of functional movements will be considered according to the ability level of each client, then to determine the number of repetitions of each movement in the first week, by taking a test, we will get the maximum number that each subject can perform the desired movement, and the number of repetitions for each movement will be 50. Up to 60% is the average maximum repetition that samples can perform the desired movement until the limit of fatigue.At the end of each week, this test will be repeated again so that the progress of the samples can be taken into account to apply appropriate overload and increase the number of each movement in each set. There is a 2 to 4 minute rest between each movement set and the next set. When the patient's tolerance and ability increases and it becomes easy for the subject to perform 30 minutes of aerobic exercise, he will enter the advanced level of exercises. Features of the advanced level of aerobic exercises (score 15 in the Borg test): In this case, the duration of the exercise will gradually increase from 30 The minute will reach 60 minutes and the person's heart rate will reach 70 to 80% of the person's maximum heart rate. In this case, the person cannot speak. Increasing the number of repetitions of exercises in each exercise set will be done using the method that was said before. (Learmont Charlotte Yan 2021)After performing aerobic exercises, strength exercises will be performed. Strength exercises: according to the results of researches that have been done before, the intensity of resistance exercises should be adjusted in such a way that the patient with multiple sclerosis after performing 10 to 15 movements reach the limits of fatigue. To perform resistance exercises, resistance against body weight and the weight of equipment used in daily life activities will be used. The intensity of the exercises will be determined according to the weight of the equipment that the subject is holding and the amount of body weight that the person must bear. In order to increase the intensity of the training, we also change the training variables such as the level of support, speed and range of motion, according to the mentioned variables, we divide each exercise into several levels.For each subject, according to the level of ability from each of the mobility parts and the movement of changing the level of pushing and pulling, we select the exercise that suits the ability of the subject, and then we gradually increase the intensity of the exercises with the increase of the subject's ability, when the subject has the ability to perform the movements. achieves one level and transfers from one level to another. During strength training, the symptoms of MS patients such as sensitivity to heat, fatigue and increased spasticity are paid attention to, and if any side effect occurs, the intensity of the training will be reduced or the type of training will be changed. We will change (Learmont Charlotte Jan 2021)In the following, we will mention the movements and functional exercises that will be performed by the subjects in this research. We will divide the movements of the human body into the parts of movement and the

movement of changing the level of pushing, pulling, and rotation, and we will give exercises for each part. Functional exercises It is used in the present research in the field of daily life activities of a person and it is similar to the movements that a person needs in performing daily life activities. The human body has four pillars of movement, which include movement and movement of surface changes, pushing and pulling, and rotation (changes in direction). The functional exercises used in this research include these four movement pillars that are performed by a set of muscles. (Juan Carlos Santana 2019)A) The movement and movement of the first exercise: walking with or without the use of an assistive device Level 1: the subject stands and takes the support surface of the walker and tries to support the weight of the body on one leg and take a step forward. Second: the level of support is gradually reduced and the subject uses a cane instead of a walker as a level of support. Third level: the subject takes one step forward without using an auxiliary device.b) Changes in the level of the first exercise: removing objects from different levels, including clothes, bags, and other items used in daily life. The first level: the person sits on a chair and bends down without removing the object, and then returns to the previous position. . The range of motion increases gradually based on the subject's ability. The second level: the person bends down and picks up the object and returns to the previous position. The weight of the object is determined based on the ability of the person and the table mentioned in the following article, and the weight of the object gradually increases.The third level: the person stands and bends and takes the support with one hand and returns to the previous position. The range of motion of bending increases gradually. The fourth level: the person stands and bends without taking a support and returns to the previous position. The range of motion increases gradually. The fifth level: the person stands and bends down without taking a support, and picks up one of the tools of daily life and returns to the previous position. The weight of the selected object is chosen according to the balance and ability of the person and gradually increases. Second exercise: exercise with hula hoop. This movement is similar to the activity of wearing pants.First level: the person stands in the middle of the hula hoop ring and holds the support with one hand and holds one side of the ring with the other hand and the therapist holds the other side of the ring and moves the ring upwards. The therapist gradually reduces the amount of help. until the subject moves the hoop alone in a limited range of motion. Second level: the person takes both sides of the hula hoop and guides the hoop from the side of the legs to the trunk without taking the support. It gradually increases the range of motion.The third exercise: sitting and getting up from the chair, first level: the person gets up from the chair by taking the support and sits on the chair again. The height of the chair is determined by the level of the person's ability and balance. The second level: the person gets up from the chair without taking the support and sits on the chair again. The height of the chair is determined by the person's ability and balance. The third exercise: going up and down the stairs. First level: the person takes the support and puts his foot on the stairs and lowers it. The height of the stairs is determined based on the ability of the subject. As the subject's ability increases gradually, the support is removed.The second level: the subject places his foot on the stairs without taking the support and lowers it. The third level: the subject puts his foot on the stairs without taking the support and lowers it. The height of the stairs gradually increases. Giving and pulling: first exercise: taking a device in the hand and moving it, such as a ball walker or other devices used in daily life activities, level 1: a person sits on a chair and holds a device in his hand and moves it forward and backward. Gives. The weight of the selected device is determined based on the person's ability and gradually increases. Second level: The person stands, holds a device in his hand and moves it forward and backward.It helps to maintain balance with the person. Gradually, the amount of help he receives from the companion decreases. The third level: the person stands and holds a device in his hand and moves it forward and backward. The level of balance of the person is determined and gradually increases. d) Rotation of the first exercise: rotating the trunk and picking up objects from different levels. First level: the person sits on a chair and performs the movement of rotating the trunk. First, the movement range of trunk rotation is small and gradually increases. Second level: the person stands and performs the trunk rotation movement. The person's companion helps him a little in maintaining balance, and gradually as the person's ability increases, the companion's help decreases. Third level: The person stands and without the companion's help performs the trunk rotation movement.The fourth level: the person stands, rotates the trunk, and then takes the tool that is used in daily life activities, such as soap, from the shelf, and then performs the rotation of the trunk to the other side. The type of selected device and its weight is based on the ability of the person and the devices that he uses in his daily life activities, and the weight of the selected device gradually increases.

Category

Rehabilitation

2

Description

Control group: The control group will receive common treatments for patients with multiple sclerosis that they want so that this research does not cause harm to these patients due to not receiving treatment.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Vahid Shaygannejad

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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https://g.co/kgs/gukHtb
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
Proportion provided by this source
50
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

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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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable