Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Action Observation therapy (AOT) on balance and kinematic parameters of gait in patients with multiple sclerosis.

Protocol summary

Study aim
Evaluation of the effect of Action Observation on Balance and kinematic parameters of gait using a gait analysis system in patients with Multiple Sclerosis (MS)

Design
A clinical trial with parallel groups including an action observation group and a control group, single-blind, randomized on 24 patients with MS.

Settings and conduct
MS patients will be included in the study if they qualify and will be randomly assigned to an intervention or control group. This study will be conducted under single-blind conditions. The assessor and therapist that assess and provide routine rehabilitation, evaluate and treat patients in separate rooms based on the assumption that each patient has undergone action observation therapy.

Participants/Inclusion and exclusion criteria
MS patients who have an EDSS score between 3 and 6, an MMSE score of more than 24, age between 18 to 45 years will be included in the study. recurrence of the disease 3 months before the intervention, pregnancy, and breastfeeding, inability to sit without support, inability to stand for at least 10 seconds with support, Other orthopedic and neurologic diseases will be excluded.

Intervention groups
The intervention group watched a 15-minute video from different angles containing exercises commonly used to improve walking in people with MS and then performed the same exercises with the help of an experienced therapist. The control group will watch a 15-minute video containing a video depicting landscapes and then perform the same exercises as the intervention group under the same conditions. The interventions will last three sessions a week for 6 weeks.

Main outcome variables
The velocity of the center of pressure; Length, width, and time of step; Stride length and time; stance time; swing time; walking speed; cadence; Kinematics of the pelvis, hip, knee, and ankle joints

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220613055155N1**
Registration date: **2022-11-12, 1401/08/21**
Registration timing: **prospective**

Last update: **2022-11-12, 1401/08/21**
Update count: **0**

Registration date
2022-11-12, 1401/08/21

Registrant information

Name
Misagh Rahimi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3627 1551

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-20, 1401/12/01

Expected recruitment end date
2023-07-23, 1402/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of Action Observation therapy (AOT) on balance and kinematic parameters of gait in patients with multiple sclerosis.

Public title
The effect of Action Observation on gait of persons with multiple sclerosis (MS)

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of spastic primary progressive, secondary progressive, relapsing-remitting MS Extensive Disability Status Scale (EDSS) Score between 3 and 6 Mini–mental state examination (MMSE) test score more than 24

Exclusion criteria:
Recurrence of MS during 3 months before intervention Pregnancy and lactation Having a psychiatric disorder or drug / alcohol abuse Inability to sit without torso support Inability to stand for at least 10 seconds with support Other neurological or orthopedic diseases of the lower extremities (musculoskeletal diseases, severe osteoarthritis, peripheral neuropathy, joint replacement) Cardiovascular diseases (recent myocardial infarction, heart failure, uncontrolled hypertension, orthostatic hypotension) participation in other clinical studies

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
A simple randomization method will be used to assign people into two groups, which will be done by selecting numbered papers (1-24) that are inside sealed envelopes, and patients will be assigned to intervention and control groups. The patient will choose one of the envelopes, even numbers are assigned to the intervention group and odd numbers to the control group. Then the selected envelope will be removed and this procedure will be repeated for the next patient.

Blinding (investigator's opinion)
Single blinded

Blinding description
The study was designed as a single-blinded study. In this intervention, the health care personnel or the clinical caregiver and the person who is in charge of the evaluation are kept blind. Before the trial started, participants were randomly divided into two groups, and other researchers were unaware of the distribution of patients. The clinical caregiver provides routine rehabilitation in the therapeutic exercise room, separate from the place where the activity observation intervention is offered, assuming that all participants will be subjected to the new intervention. Participants are asked not to discuss the movie they saw with the clinical caregiver. In addition, the evaluator evaluates the participants in a separate laboratory presuming all patients will undergo observation. We ask patients not to discuss the film they have seen with the evaluator. The evaluator and clinical supervisor are unaware of what is happening in the new intervention room as the leading researcher presents videos in a separate room.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz Rehabilitation School

Street address
School of Rehabilitation, Abiverdi 1 St., Chamran Blvd., Shiraz, Fars, Iran

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Shiraz

Province
Fars

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7194733669

Approval date
2022-07-20, 1401/04/29

Ethics committee reference number
IR.SUMS.REHAB.REC.1401.021

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
The center of pressure velocity (COPV)

Timepoint

at the beginning of the study (before the start of the intervention), after the end of the intervention (6 weeks after the start of the intervention) and one month after the end of the intervention

Method of measurement

Force plate

2

Description

step length

Timepoint

At the beginning of the study (before the start of the intervention), after the end of the intervention (6 weeks after the start of the intervention), and one month after the end of the intervention

Method of measurement

3D Motion capture cameras and gait analyzing system

3

Description

step width

Timepoint

At the beginning of the study (before the start of the intervention), after the end of the intervention (6 weeks after the start of the intervention), and one month after the end of the intervention

Method of measurement

3D Motion capture cameras and gait analyzing system

4

Description

step time

Timepoint

At the beginning of the study (before the start of the intervention), after the end of the intervention (6 weeks after the start of the intervention) and one month after the end of the intervention

Method of measurement

3D Motion capture cameras and gait analyzing system

5

Description

Gait velocity (meters per second)

Timepoint

At the beginning of the study (before the start of the intervention), after the end of the intervention (6 weeks after the start of the intervention) and one month after the end of the intervention

Method of measurement

3D Motion capture cameras and gait analyzing system

6

Description

stride length

Timepoint

At the beginning of the study (before the start of the intervention), after the end of the intervention (6 weeks after the start of the intervention) and one month after the end of the intervention

Method of measurement

3D Motion capture cameras and gait analyzing system

7

Description

Stride time

Timepoint

At the beginning of the study (before the start of the intervention), after the end of the intervention (6 weeks after the start of the intervention) and one month after the end of the intervention

Method of measurement

3D Motion capture cameras and gait analyzing system

8

Description

Gait cadence (steps per minute)

Timepoint

At the beginning of the study (before the start of the intervention), after the end of the intervention (6 weeks after the start of the intervention) and one month after the end of the intervention

Method of measurement

3D Motion capture cameras and gait analyzing system

9

Description

ankle kinematics

Timepoint

At the beginning of the study (before the start of the intervention), after the end of the intervention (6 weeks after the start of the intervention) and one month after the end of the intervention

Method of measurement

3D Motion capture cameras and gait analyzing system

10

Description

knee kinematics

Timepoint

At the beginning of the study (before the start of the intervention), after the end of the intervention (6 weeks after the start of the intervention) and one month after the end of the intervention

Method of measurement

3D Motion capture cameras and gait analyzing system

11

Description

hip kinematics

Timepoint

At the beginning of the study (before the start of the intervention), after the end of the intervention (6 weeks after the start of the intervention) and one month after the end of the intervention

Method of measurement

3D Motion capture cameras and gait analyzing system

12

Description
Pelvis kinematics
Timepoint
At the beginning of the study (before the start of the intervention), after the end of the intervention (6 weeks after the start of the intervention) and one month after the end of the intervention
Method of measurement
3D Motion capture cameras and gait analyzing system

13

Description
stance time
Timepoint
At the beginning of the study (before the start of the intervention), after the end of the intervention (6 weeks after the start of the intervention) and one month after the end of the intervention
Method of measurement
3D Motion capture cameras and gait analyzing system

14

Description
swing time
Timepoint
At the beginning of the study (before the start of the intervention), after the end of the intervention (6 weeks after the start of the intervention) and one month after the end of the intervention
Method of measurement
3D Motion capture cameras and gait analyzing system

Secondary outcomes

empty

Intervention groups

1

Description
Action observation intervention group: This group includes 12 patients with MS who are included in the study based on the inclusion criteria. In the first stage, the subjects of this group undergo a 30-minute routine rehabilitation, which will be performed by a blind occupational therapist familiar with the MS rehabilitation program. The physical training programs will focus on stretching exercises, balance, walking, and muscle strengthening. Then, in the second stage, the main researcher shows the video clips to the patients for 15 minutes. Then all the displayed exercises will be practiced by the patient and the main researcher for 15 minutes. To watch videos, a person sits on a comfortable chair in front of a 19-inch monitor 100 cm away from them. While watching the video, people are asked to watch carefully and do nothing. The videos in the intervention group include exercises related to walking, crossing an obstacle, going up and down stairs, and standing up and sitting on a chair, which was performed by a healthy adult man and was taken from the front, back, and side angles. Each exercise is shown for three minutes and the person is given one-minute rest between each series of videos. Both groups will receive three treatment sessions per week for six consecutive weeks.
Category
Rehabilitation

2

Description
control group: This group includes 12 patients with MS who are included in the study based on the inclusion criteria after receiving a 30-minute routine rehabilitation that includes stretching, strengthening, and balance exercises, in the second stage, videos include images of landscapes. They will observe nature videos, without any movement content for 15 minutes, and then they will receive the same exercise activities as the action observation intervention group. In fact, patients in the control group will receive the same rehabilitation protocol as the intervention group. During the sessions, they will simultaneously watch a video containing images of natural landscapes without moving content. In order to comply with ethical issues, a few Action observation treatment sessions will be conducted after the project's completion. Both groups will receive three treatment sessions per week for six consecutive weeks.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz Rehabilitation School
Full name of responsible person
Misagh Rahimi
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School of Rehabilitation, Abiverdi 1 St., Chamran Blvd., Shiraz, Fars, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Misagh Rahimi

Position
Clinical expert

Latest degree
Bachelor

Other areas of specialty/work
Occupational Therapy

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All the data of this study can be shared after de-identifying the participants.

When the data will become available and for how long

The data of this study will be accessible three months after the results are published.

To whom data/document is available

Researchers from academic and scientific institutions will have access to this study's data

Under which criteria data/document could be used

Using this study does not require any special conditions.

From where data/document is obtainable

To receive data and documents, please refer to Dr. Abolqasem Fallahzadeh, Professor of Shiraz Rehabilitation Faculty. Phone: 07136271551 E-mail: A_Fallahzadeh@Sums.ac.ir Address: Shiraz Faculty of Rehabilitation Sciences, 1 Abivardi Street, Chamran Blvd.

What processes are involved for a request to access data/document

A letter of request is enough to receive data.

Comments