Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The comparison of the immediate effects of UD-Flex and PLS orthoses on spatiotemporal gait parameters in individuals with Multiple Sclerosis and Drop foot: A randomized crossover clinical study

Protocol summary

Study aim

Comparison of the immediate effect of UD-Flex and PLS orthoses on spatiotemporal gait parameters in individuals with multiple sclerosis and foot drop

Design

A randomized,single-blind,cross-over clinical trial with 12 participants

Settings and conduct

Samples will be selected from available individuals with multiple sclerosis and foot drop at the outpatient clinics of Kashani Hospital, Isfahan, Iran. Blinding of the participants was not possible because they could see which intervention they were wearing.By coding the data, the data analyst was blinded. To prevent assessment bias, automated devices were used to measure the gait variables.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Individuals with multiple sclerosis and foot drop with disability score between 4 and 6 and able to walk without the assistance of a device or another person. Exclusion Criteria: Individuals who have had a relapse (exacerbation) of the disease within the past 3 months as confirmed by a physician. Individuals with impaired consciousness who cannot provide informed consent. Musculoskeletal disorders that impair the individual's walking. Individuals with severe cardiac or respiratory problems that prevent the patient's participation and the performance of tests.

Intervention groups

Intervention1: Custom-made PLS ankle-foot orthosis fabricated at the Orthotics and Prosthetics Clinic of Kashani Hospital, Isfahan, Iran, for each patient.It is placed behind the calf and ankle, and the heel has no contact with the ground.Intervention2: Prefabricated UD-Flex orthosis from ADVANFIT INC, Japan,placed in front of the ankle,with the heel having direct contact with the ground.Control:Barefoot (without orthosis).A 10-minute rest period is provided between each test to ensure that fatigue does not affect the results.

Main outcome variables

Cadence,Walking speed,Step length,step width,Double support time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231209060299N1**
Registration date: **2026-05-29, 1405/03/08**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-29, 1405/03/08**
Update count: **0**

Registration date

2026-05-29, 1405/03/08

Registrant information

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Hossein Asiaemehr
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-21, 1405/02/31

Expected recruitment end date

2026-05-31, 1405/03/10

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison of the immediate effects of UD-Flex and PLS orthoses on spatiotemporal gait parameters in individuals with Multiple Sclerosis and Drop foot: A randomized crossover clinical study

Public title
The effect of orthoses on gait in individuals with multiple sclerosis and foot drop.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
People with relapsing-remitting multiple sclerosis who are in the remission phase. individuals with drop foot. Maximum spasticity in the ankle plantar flexor muscles should be grade 2 according to the Modified Ashworth Scale (MAS). The patient's disability score should be between 4 and 6. Patients aged 20–50 years. The individual should be able to walk 20 meters without assistance from others or with the use of a walking aid.
Exclusion criteria:
Individuals who have had a relapse (exacerbation) of the disease within the past 3 months, as confirmed by a physician. Individuals with impaired consciousness who cannot provide informed consent. Musculoskeletal disorders that impair the individual's walking. Individuals who have severe cardiac or respiratory problems that prevent the patient's participation and the performance of the tests. History of fractures or surgeries of the lower limbs, ankle sprain, osteoarthritis, and pain that severely limits walking. Individuals with psychiatric disorders.
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **12**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method in this study was simple randomization. Due to the cross-over design and the random order of all three conditions (barefoot, PLS orthosis, and UD-Flex orthosis), simple randomization was used to determine the sequence of testing. Given the limited sample size (12 participants) and the absence of different subgroups, block or stratified randomization methods were not required, and there were no randomization layers. The unit of randomization was the individual, and each participant independently received their own sequence of interventions. Each of the 6 possible sequences (3!) was written on cards and placed inside opaque, non-visible envelopes. The envelopes were numbered and sealed by an individual independent of the researcher. The random sequence was generated using a random number table by a person independent of the researcher before the start of the study. Considering the three conditions (barefoot, PLS orthosis, UD-Flex orthosis) and the completely random order of their execution, all 6 possible permutations (3!) were considered equally likely. For each participant, a two-digit random number was selected from the random number table, and based on the remainder of division by 6 (0 to 5), one of the 6 sequences was randomly determined. Allocation concealment was performed using opaque, sealed, sequentially numbered envelopes. The researcher was unaware of the sequence of conditions until the time of testing and opening the envelope corresponding to each patient. After recording the patient's characteristics and confirming the inclusion criteria, the corresponding envelope was opened in numerical order, and the test sequence was executed according to the envelope's contents. This method prevented bias in the allocation of intervention order. An important point is that the barefoot condition was considered the control condition (without intervention), and the randomization of its order did not change its control nature. A 10-minute rest period was provided between different tests to eliminate fatigue and carryover effects.
Blinding (investigator's opinion)
Single blinded
Blinding description
Since all participants are assessed under all three conditions (and are not divided into intervention and control groups), it is not possible to blind the participants or the assessor. To maintain single blinding, the data analyst will be unaware of how the intervention (type of orthosis) was allocated in each test session. For this purpose, all raw data collected by the motion analysis system will be coded before being delivered to the analyst, so that they will not be able to identify the type of intervention.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Nursing, Rehabilitation & Management schools- Isfahan

Street address
School of Rehabilitation, Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2026-04-18, 1405/01/29
Ethics committee reference number
IR.MUI.NUREMA.REC.1405.005

Health conditions studied

1

Description of health condition studied
Foot drop in multiple sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Cadence
Timepoint
Measurements are performed randomly under three conditions: barefoot, immediately after wearing the PLS orthosis following a 5-minute accommodation period, and immediately after wearing the UD-Flex orthosis following a 5-minute accommodation period. All measurements are conducted in a single session to assess the immediate effect, and there is no follow-up period (daily or weekly). The assessment frequency is only once per condition.
Method of measurement
Qualisys motion capture system

2

Description
Walking speed
Timepoint
Measurements are performed randomly under three conditions: barefoot, immediately after wearing the PLS orthosis following a 5-minute accommodation period, and immediately after wearing the UD-Flex orthosis following a 5-minute accommodation period. All measurements are conducted in a single session to assess the immediate effect, and there is no follow-up period (daily or weekly). The assessment frequency is only once per condition.
Method of measurement
Qualisys motion capture system

3

Description
Step length
Timepoint
Measurements are performed randomly under three conditions: barefoot, immediately after wearing the PLS orthosis following a 5-minute accommodation period, and immediately after wearing the UD-Flex orthosis following a 5-minute accommodation period. All measurements are conducted in a single session to assess the immediate effect, and there is no follow-up period (daily or weekly). The assessment frequency is only once per condition.
Method of measurement
Qualisys motion capture system

4

Description
Step width
Timepoint
Measurements are performed randomly under three conditions: barefoot, immediately after wearing the PLS orthosis following a 5-minute accommodation period, and immediately after wearing the UD-Flex orthosis following a 5-minute accommodation period. All measurements are conducted in a single session to assess the immediate effect, and there is no follow-up period (daily or weekly). The assessment frequency is only once per condition.
Method of measurement
Qualisys motion capture system

5

Description
Double support time
Timepoint
Measurements are performed randomly under three conditions: barefoot, immediately after wearing the PLS orthosis following a 5-minute accommodation period, and immediately after wearing the UD-Flex orthosis following a 5-minute accommodation period. All measurements are conducted in a single session to assess the immediate effect, and there is no follow-up period (daily or weekly). The assessment frequency is only once per condition.
Method of measurement
Qualisys motion capture system

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1: PLS orthosis; a type of ankle-foot orthosis placed on the posterior side of the calf and ankle, custom-made for each patient at the Orthotics and

Prosthetics Clinic of Kashani Hospital, Isfahan, Iran. This orthosis is made of thermoplastic polypropylene material. It also has a non-slip rubber footplate and is worn without shoes. After putting on the orthosis, the participant walks along a 7-meter path, and their movements are recorded by a motion analysis system. It is worth noting that the effect of the orthosis is immediate and short-term, and its effect disappears as soon as the orthosis is removed. Nevertheless, a 10-minute rest period is provided between different tests to eliminate fatigue and carryover effects.

Category

Rehabilitation

2

Description

Intervention Group 2: UD-Flex orthosis; a prefabricated orthosis manufactured by ADVANFIT INC., Japan, which is placed on the anterior side of the ankle, allowing the heel to freely contact the ground during walking. After precise measurement of each patient's foot dimensions (foot length, foot width, and calf circumference), the appropriate orthosis size is selected from the available standard sizes based on the manufacturer's sizing chart. The individual wears this orthosis without shoes. After donning the orthosis, the participant walks along a 7-meter path, and their movements are recorded by a motion analysis system. It is worth noting that the effect of the orthosis is immediate and short-term, and its effect disappears as soon as the orthosis is removed. Nevertheless, a 10-minute rest period is provided between different tests to eliminate fatigue and carryover effects.

Category

Rehabilitation

3

Description

Control Group: Barefoot (without orthosis); the barefoot condition is considered the control condition (without intervention), in which the participant walks barefoot along a 7-meter path, and their movements are recorded by a motion analysis system. A 10-minute rest period is provided between different tests to eliminate fatigue and carryover effects.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Kashani Educational and Medical Center, Isfahan

Full name of responsible person

Dr.Vahid Shaygannejad

Street address

Ayatollah Kashani Educational and Therapeutic Center (Jouzdan Neighborhood), Ayatollah Kashani Miyani Street, Mirdamad, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Gholamreza Asgari

Street address

Building No. 4, Vice Chancellery for Research and Technology, Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran

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askari@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person
Dr.Hossein Asiyaeimehr

Position
Assistant Professor and Faculty Member of the Department of Orthotics and Prosthetics

Latest degree
Ph.D.

Other areas of specialty/work
Orthotics and Prosthetics

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is a plan to make this available

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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Study data (excluding personal information) will be shared with other researchers.

When the data will become available and for how long
The data will be shared after the publication of the results or a summary of the data.

To whom data/document is available
The data will be shared solely for academic purposes.

Under which criteria data/document could be used
The data will be shared for teaching and research purposes of the applicants.

From where data/document is obtainable
Individuals can request the information from the designated responsible person.

What processes are involved for a request to access data/document
Requests must be sent via email (asiyaeimehr@rehab.mui.ac.ir).

Comments