Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Effect of an Eight-Week Combined Protocol (Body Weight-Supported Treadmill Training) on Weight Bearing, Motor Function, Respiratory Function, and Quality of Life in Patients with Incomplete Paraplegic Spinal Cord Injury

Protocol summary

Study aim

This study investigates the effects of an eight-week combined protocol (treadmill training with body-weight support) on weight-bearing tolerance, motor function, pulmonary indices, and quality of life in patients with incomplete paraplegic spinal cord injury

Design

The target population for this study consists of individuals aged 20 to 50 who sustained their injuries at least one year prior. Participants were selected using purposive sampling and randomly assigned to either the intervention group or the control group.

Settings and conduct

The selected individuals are from the "Hana Charity Association of Isfahan Province"; this specific group was chosen based on age range and level of impairment to ensure they are capable of performing the intended exercises. Conducting the sampling at this center provides us with access to standard equipment.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with incomplete paraplegic spinal cord injury confirmed by a physician and ASIA assessment Age 20–50 years Presence of sensation and movement in the lower limbs Willingness to participate in the study Exclusion Criteria: Vestibular or balance disorders Metabolic, organic, or other diseases unrelated to spinal cord injury Any condition preventing participation in the study Voluntary withdrawal Irregular attendance at training sessions

Intervention groups

A minimum of 30 participants was required for the study: 15 participants for treadmill training with body-weight support and 15 participants for the control group. However, to increase the precision of the study and account for potential withdrawals or participant unavailability, a total of 37 individuals were evaluated.

Main outcome variables

Sitting balance, quality of life, respiratory function, hip and knee muscle strength, core muscle endurance, motor function, weight-bearing ability.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260817070688N1**
Registration date: **2026-08-20, 1405/05/29**
Registration timing: **prospective**

Last update: **2026-08-20, 1405/05/29**
Update count: **0**

Registration date

2026-08-20, 1405/05/29

Registrant information

Name

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Name of organization / entity

The University of Isfshan

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-23, 1405/06/01

Expected recruitment end date
2026-10-22, 1405/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of an Eight-Week Combined Protocol (Body Weight-Supported Treadmill Training) on Weight Bearing, Motor Function, Respiratory Function, and Quality of Life in Patients with Incomplete Paraplegic Spinal Cord Injury

Public title
The effect of body-weight-supported treadmill training
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with spinal cord injury (incomplete paraplegia), based on specialist diagnosis and the ASIA assessment. Age range of 20 to 50 years Presence of sensation and movement in the lower limbs Voluntary consent to participate in the study Walking with an assistive device such as a brace
Exclusion criteria:
Vestibular and coordination disorders Suffering from any metabolic, organic, or similar disease—excluding spinal cord injury. Occurrence of any unforeseen problem that makes the patient's participation in the study impossible. Voluntary withdrawal from participation in the research Irregular attendance at training sessions Pregnancy
Age
From **20 years** old to **50 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
Participants are assigned to two groups an intervention group (weight-supported treadmill training) and a control group (non-treadmill training)using a paired randomization method based on the ASIA scale and the Randomizer.org software. This approach maintains balance between the groups and minimizes selection bias.
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 the University of Isfahan
Street address
No. 16, Ettehad Alley, Shohada Street, Imam Khomeini Street
City
Isfahan
Province
Isfehan
Postal code
8195641790
Approval date
2026-06-27, 1405/04/06
Ethics committee reference number
IR.UI.REC.1405.087

Health conditions studied

1

Description of health condition studied
People with incomplete spinal cord injury
ICD-10 code
S34
ICD-10 code description
Injury of lumbar and sacral spinal cord and nerves at abdomen, lower back and pelvis level

Primary outcomes

1

Description
The maximum functional reach distance in the modified MFRT, measured in centimeters.
Timepoint
Measurements were taken at two time points: before the start of the intervention (pre-test) and immediately after the completion of the eight-week intervention (post-test).
Method of measurement
Modified Functional Reach Test

2

Description
The flexor strength of the hip and knee muscles is measured using a dynamometer and expressed in Newtons.
Timepoint
Measurements were taken at two time points: before the start of the intervention (pre-test) and immediately after the completion of the eight-week intervention (post-test).
Method of measurement

Dynamometer Device

3

Description
Hip and knee extensor muscle strength, measured in Newtons using a dynamometer.
Timepoint
Measurements were taken at two time points: before the start of the intervention (pre-test) and immediately after the completion of the eight-week intervention (post-test).
Method of measurement
Dynamometer device

4

Description
Core muscle endurance is based on the duration for which a modified plank position is maintained, measured in seconds.
Timepoint
Measurements were taken at two time points: before the start of the intervention (pre-test) and immediately after the completion of the eight-week intervention (post-test).
Method of measurement
Modified Plank Test

5

Description
Forced expiratory volume in the first second (FEV1) is measured in liters using a digital spirometer.
Timepoint
Measurements were taken at two time points: before the start of the intervention (pre-test) and immediately after the completion of the eight-week intervention (post-test).
Method of measurement
Digital spirometry device

6

Description
Forced Vital Capacity (FVC) is measured by digital spirometry and expressed in liters.
Timepoint
Measurements were taken at two time points: before the start of the intervention (pre-test) and immediately after the completion of the eight-week intervention (post-test).
Method of measurement
Digital spirometry device

7

Description
The wheelchair skills test, which is conducted based on the researcher's objective assessment of wheelchair skills and supplemented by a questionnaire
Timepoint
Measurements were taken at two time points: before the start of the intervention (pre-test) and immediately after the completion of the eight-week intervention (post-test).
Method of measurement
wheelchair skills test

8

Description
Measuring the amount of weight-bearing on the leg during treadmill walking and the precise amount of weight transferred to the weight-support device.
Timepoint
Measurements were taken at two time points: before the start of the intervention (pre-test) and immediately after the completion of the eight-week intervention (post-test).
Method of measurement
Load cell

9

Description
Energy expenditure is determined through measurement tests based on distance covered, walking time, and heart rate
Timepoint
Measurements were taken at two time points: before the start of the intervention (pre-test) and immediately after the completion of the eight-week intervention (post-test).
Method of measurement
Physiological Cost Index

10

Description
Walking speed measured in meters per second based on tests conducted over a designated course using an assistive device is expressed in meters per second.
Timepoint
Measurements were taken at two time points: before the start of the intervention (pre-test) and immediately after the completion of the eight-week intervention (post-test).
Method of measurement
10-Meter walk test

11

Description
The quality of life index score, based on the quality of life index questionnaire.
Timepoint
Measurements were taken at two time points: before the start of the intervention (pre-test) and immediately after the completion of the eight-week intervention (post-test).
Method of measurement
Quality of Life Index

Secondary outcomes

1

Description
The score on the quality of life questionnaire, which is measured in the pre-test and post-test.
Timepoint
Measurements were taken at two time points: before the start of the intervention (pre-test) and immediately after the completion of the 8-week intervention (post-test).
Method of measurement

66-Item Quality of Life Index Questionnaire: 33 Questions on Importance and 33 Questions on Satisfaction

Intervention groups

1

Description
Intervention group: Participants undergo an eight-week program consisting of three sessions per week; each 45-minute session involves weight-supported treadmill walking and upper-limb exercises performed under the supervision of a therapist. The training regimen is progressively adjusted according to the individuals' capabilities, and all exercises are standardized for every patient and conducted under the supervision of the researcher.

Category
Rehabilitation

2

Description
Control group: All study participants perform a range of exercises—including balance, endurance, and strength training, but excluding treadmill walking—three times a week for eight weeks, with each session lasting 45 minutes; all exercises are conducted under the supervision of a therapist.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan Spinal Cord Injury Support Charity (Hana)

Full name of responsible person
Dr.Gholamreza Pesteh

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Shahidan Teimouri Alley, Nabavi-Manesh Street, Atashgah Street, Isfahan

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Email
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Web page address
https://hana-charity.org

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of Isfahan

Full name of responsible person
Dr. Mohammadreza Abedi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
University of Isfahan

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
The University of Isfahan

Full name of responsible person
Fatemeh Taheri

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Sports Pathology and Corrective Movements

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

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