

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 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

Fatemeh Taheri

Name of organization / entity

The University of Isfahan

Country

Iran (Islamic Republic of)

Phone

+98 31 3580 3822

Email address

f.taheri79@spr.ui.ac.ir

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

Isfahan

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

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

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

Street address

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

City

Isfahan

Province

Isfahan

Postal code

8188753664

Phone

+98 31 3766 0176

Email

info@hana-charity.org

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

Street address

University of Isfahan, Azadi Square, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673441

Phone

+98 31 3793 2128

Email

info@ui.ac.ir

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

Street address

No. 16, Ettehad Alley, Shohada Street, Imam Khomeini Street

City

Isfahan

Province

Isfahan

Postal code

8195641790

Phone

+98 31 3580 3822

Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

The University of Isfahan

Full name of responsible person

Dr.Gholamali Ghasemi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

PhD in Sports Pathology and Corrective Movements

Street address

Faculty of Sports Sciences, University of Isfahan, Azadi Square, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673441

Phone

+98 31 3793 2128

Email

gh.ghasemi@spr.ui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

The University of Isfahan

Full name of responsible person

Dr.Gholamali Ghasemi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

PhD in Sports Pathology and Corrective Movements

Street address

Faculty of Sports Sciences, University of Isfahan, Azadi Square, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673441

Phone

+98 31 3793 2128

Email

gh.ghasemi@spr.ui.ac.ir

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