Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the Effect of Thoracolumbosacral Orthosis with Neurological-Mechanical Features on Trunk Control, Seating Balance, Respiratory Function, and Pain in Individuals with Spinal Cord Injury

Protocol summary

Study aim

This study investigates the effects of neuro-mechanical and conventional thoracolumbosacral orthoses on trunk control, sitting balance, respiratory function, and pain in individuals with spinal cord injury, and compares the two to guide the development of an optimized orthosis for improved sensorimotor function and rehabilitation.

Design

This is an exploratory randomized controlled trial with a two-group parallel design on 8 patients. Blinding will not be performed in this study.

Settings and conduct

In the first session, participants visit the Technical orthopedic clinic at the University of Social Welfare and Rehabilitation Sciences, where eligibility criteria are assessed and initial measurements for orthosis fabrication are performed. In the second session, participants are randomly assigned to groups, and tests are conducted first without and then with the orthosis in randomized order. Orthoses are used daily for four weeks; the intervention group activates the sensory mechanism twice daily for 20 minutes. After four weeks, tests are repeated.

Participants/Inclusion and exclusion criteria

Participants must be ≥18 years old with T8–T12 spinal cord injury impairing trunk stability and requiring a thoracolumbosacral orthosis. At least 12 months post-injury, with no orthosis used in the past 2–3 months. ASIA B–D and neuropathic pain >4. Exclusions: severe musculoskeletal, cognitive, psychological disorders, comorbidities, implants, or pregnancy.

Intervention groups

In the intervention group, participants use a thoracolumbosacral orthosis with neuro-mechanical features, activating its sensory stimulation mechanism twice daily; the control group uses a conventional thoracolumbosacral orthosis without these features.

Main outcome variables

Trunk control, sitting balance, respiratory function, and pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250902067106N1**
Registration date: **2025-09-19, 1404/06/28**
Registration timing: **registered_while_recruiting**

Last update: **2025-09-19, 1404/06/28**
Update count: **0**

Registration date

2025-09-19, 1404/06/28

Registrant information

Name

Yasaman Zamanpour

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-16, 1404/06/25

Expected recruitment end date

2026-03-20, 1404/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the Effect of Thoracolumbosacral Orthosis with Neurological-Mechanical Features on Trunk Control, Seating Balance, Respiratory Function, and Pain in Individuals with Spinal Cord Injury

Public title
Investigating the Effect of Thoracolumbosacral Orthosis with Neurological-Mechanical Features in Individuals with Spinal Cord Injury
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Participants in this study must be at least 18 years old. Individuals with a spinal cord injury at the T8 to T12 level, in such a way that trunk stability is impaired and, according to the physician's judgment, require the use of a thoracolumbosacral orthosis. At least 12 months must have passed since the injury for individuals to be considered as chronic cases, as the plateau of neurological recovery usually occurs after this period. Participants must not have used a spinal orthosis during the past two to three months. Individuals must be classified as grade B, C, or D according to the American Spinal Injury Association (ASIA) Impairment Scale. The presence of neuropathic pain, assessed using the Neuropathic Pain Scale, with a score greater than 4 indicating the existence of this type of pain.
Exclusion criteria:
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **8**
Randomization (investigator's opinion)
Randomized
Randomization description
In this clinical trial, samples will be selected using convenience sampling and subsequently assigned to one of two groups (Thoracolumbosacral Orthosis with Neurological-Mechanical Features, Traditional Thoracolumbosacral Orthosis) utilizing the block randomization method. The unit of randomization is individual participants. An equal number of participants will be allocated to each study group, following a 1:1:1:1 ratio. To generate a random sequence of blocks, each group will be assigned a specific code, and the randomizer.org website will be employed. The order of participant entry will be determined using two blocks of size four. Once individuals meet the inclusion criteria and sign the consent form to participate in the study, they will be assigned to one of the groups based on the randomly selected block sequence.
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 Social Welfare and Rehabilitation Sciences
Street address
kodakyar Ave, daneshjo Blvd, Evin, Velenjak
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Postal code
1985713871
Approval date
2025-09-03, 1404/06/12
Ethics committee reference number
IR.USWR.REC.1404.108

Health conditions studied

1

Description of health condition studied
Lumbar level spinal cord injury
ICD-10 code
S34.1
ICD-10 code description
Other and unspecified injury of lumbar and sacral spinal cord

Primary outcomes

1

Description
Trunk control score on the Trunk Assessment Scale Score
Timepoint
Before, immediately while using , and four weeks after wearing the orthoses
Method of measurement
Trunk Assessment Scale Score

2

Description
Sitting balance score on the Sitting Balance Score
Timepoint
Before, immediately while using , and four weeks after wearing the orthoses
Method of measurement
Sitting Balance Score

3

Description
Respiratory function score on the Breath-Holding Time test
Timepoint
Before, immediately while using , and four weeks after wearing the orthoses
Method of measurement
Breath Holding Time

4

Description
Pain intensity measured on the Visual Analog Scale for pain
Timepoint
Before, immediately while using , and four weeks after wearing the orthoses
Method of measurement
Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
Participants in this group will use a thoracolumbosacral orthosis with neuro-mechanical features. After receiving training on proper usage and completing baseline tests without the orthosis, participants will wear the orthosis and repeat the tests while using it. Following this session, participants must use the orthosis daily for four weeks, and to activate its tension mechanism, they will use it twice a day for 20 minutes per session according to the specified schedule.
Category
Rehabilitation

2

Description
Control group: Participants in this group will use a conventional thoracolumbosacral orthosis. After receiving training on proper usage and completing baseline tests without the orthosis, participants will wear the orthosis and repeat the tests while using it. Following this session, participants must use the orthosis daily for four weeks, without any neuro-mechanical features or active tension mechanism.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Technical orthopedic clinic of rehabilitation school, University of Social Welfare and Rehabilitatio
Full name of responsible person
Reza Vhab Kashani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Mohammad saeed khanjani
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Kodakyar Ave., Daneshjo Blvd., Evin, Velenjak
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sa.khanjani@uswr.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Mahmood Bahramizadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Orthopedics

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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

The study information (data related to the scores of the Trunk Assessment Scale Score, Sitting Balance Score, Breath Holding Time, and Visual Analog Scale) will be shared with other researchers.

When the data will become available and for how long

Information is shared after the results are printed or summarized.

To whom data/document is available

Researchers working in academic institutions.

Under which criteria data/document could be used

By performing statistical tests on the data, the applicants can evaluate the results of using the interventions of this study on on trunk Control, seating balance, respiratory function, and pain and use these data to conduct meta-analysis review studies.

From where data/document is obtainable

Individuals can request information from the person in charge.

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

Requests should be sent to Dr. Mahmood Bahramizadeh (ma.bahramizadeh@uswr.ac.ir).

Comments