

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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  $\geq 18$  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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3366 3728

##### Email address

yas.zamanpour@uswr.ac.ir

##### 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

**City**

Tehran

**Province**

Tehran

**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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Kodakyar Ave., Daneshjo Blvd., Evin, Velenjak

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#### **Phone**

+98 21 7173 2000

#### **Email**

mbzoandp@gmail.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

University of social welfare and rehabilitation sciences

#### **Full name of responsible person**

Mohammad saeed khanjani

#### **Street address**

Kodakyar Ave., Daneshjo Blvd., Evin, Velenjak

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#### **Phone**

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#### **Email**

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**

**Contact**

**Name of organization / entity**

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**Position**

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**Latest degree**

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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**