Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Effects of Body Weight Supported Treadmill Training along with Electrical Stimulation on Functional Ambulation, Pain and Quality Of Life in Patients with Incomplete Traumatic Spinal Cord Injury

Protocol summary

Study aim

Assessment of the impact of BWSTT in combination with electrical stimulation on functional ambulation in patients with incomplete traumatic spinal cord injuries.

Design

Three arm parallel group, randomized trial with blinded patients and data analyst. Simple randomization and concealment of the randomization sequence was performed using R software.

Settings and conduct

This single center study includes 81 patients having incomplete traumatic spinal cord injuries. The patients will be randomly divided into 3 groups, namely Group I (BWSTT + ES + conventional physical therapy), Group II (BWSTT + conventional physical therapy), and Group III (conventional physical therapy only). Patients will be assessed in terms of the study outcomes before treatment and 6 ,12 week after intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria Patients aged between 16-55 years Both male and female patients Patients with incomplete traumatic SCIs (ASIA scale B, C, D) Patients with stable spines and in the sub-acute rehabilitation phase Patients with mild neuropathic pain (1-3 on Visual Analogue Scale) Exclusion criteria Patients in acute phase of rehabilitation Patients with pressure sores, infections or other complications Patients with visual impairments that may impact participation in rehabilitation

Intervention groups

Intervention group 1: Participants in this group will receive body weight supported treadmill training along with electrical stimulation and conventional physical therapy. Intervention group 2: Participants in this group will receive body weight supported treadmill training and conventional physical therapy Control group: Participants in this group will receive conventional physical therapy only.

Main outcome variables

Functional ambulation, neuropathic pain level and inflammatory pain markers (CRP, IL-6, IL-2), quality of life and activities of daily living.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230615058487N1**
Registration date: **2023-07-29, 1402/05/07**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-29, 1402/05/07**
Update count: **0**

Registration date

2023-07-29, 1402/05/07

Registrant information

Name

Amir Zeb

Name of organization / entity

Riphah International University

Country

Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-13, 1402/02/23

Expected recruitment end date

2023-12-31, 1402/10/10

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

Scientific title
Effects of Body Weight Supported Treadmill Training along with Electrical Stimulation on Functional Ambulation, Pain and Quality Of Life in Patients with Incomplete Traumatic Spinal Cord Injury

Public title
Effects of body weight supported treadmill training along with electrical stimulation on functional ambulation, pain and quality of life in patients with incomplete traumatic-spinal cord injury.
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged between 16-55 years Both male and female patients Patients with incomplete traumatic SCIs (ASIA scale B, C, D) Patients with stable spines Patients in the sub-acute rehabilitation phase Patients with mild neuropathic pain (1-3 on VAS)
Exclusion criteria:
Patients in acute phase of rehabilitation Patients with pressure sores, infections or other complications Patients with visual impairments that may impact participation in rehabilitation
Age
From **16 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **81**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients were randomly assigned to three groups. The randomization process for assigning participants to these groups was performed using R software, ensuring a randomized distribution of patients among the three treatment groups. Group I: Participants in this group were designated to receive Body Weight Supported Treadmill Training (BWSTT) along with electrical stimulation (ES) in addition to conventional physical therapy. Group II: Participants in this group were assigned to receive BWSTT and conventional physical therapy. Group III: Participants in this group were assigned to receive conventional physical therapy only.
Blinding (investigator's opinion)
Double blinded
Blinding description
A double-blind design was implemented to minimize bias and ensure the integrity of the research. The blinding process began with the invitation and recruitment of patients to participate in the study. During this stage, the patients were unaware of the specific treatment group they would be assigned to. The blinding will be maintained by not disclosing any information regarding the intervention groups. Following the recruitment phase, the patients were divided into their respective intervention groups, namely Group I (BWSTT + ES + conventional physical therapy), Group II (BWSTT + conventional physical therapy), and Group III (conventional physical therapy only). The allocation of patients into these groups was carried out by an independent individual not involved in the direct treatment or assessment of participants. This individual was also blinded to the nature of the interventions. The data analyst responsible for analyzing the collected data will remain unaware of the participants' group assignments and the specific treatments received by each group. This individual will be conducting the analysis without any knowledge that could potentially bias the interpretation of the results. By employing a double-blind approach, both the patients and the data analyst were kept unaware of the treatment allocations. This blinding methodology prevents potential biases from influencing the results, thereby enhancing the scientific validity and reliability of our study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research & Ethics committee of College of Rehabilitation and Allied Health Sciences(FRAHS)
Street address
Madar-e-Millat Road, Quaid-e-Azam Industrial Estate Quaid e Azam Industrial Estate
City
Lahore
Postal code
2023
Approval date
2023-03-07, 1401/12/16
Ethics committee reference number
REC/RCR& AHS/1011

Health conditions studied

1

Description of health condition studied
Spinal cord injury
ICD-10 code
T09.3
ICD-10 code description
Injury of spinal cord, level unspecified

Primary outcomes

1

Description
Functional ambulation
Timepoint
Before intervention and , 6 ,12 week after intervention
Method of measurement
Walking Index for Spinal Cord Injuries-II,Spinal Cord Independence Measure (SCIM),6-Minute Walk Test (6MWT) and 10-Meter Walk Test

Secondary outcomes

1

Description
Neuropathic pain level and inflammatory pain markers, and Quality Life Index for spinal cord injury
Timepoint
Before intervention and 6,12 weeks after intervention
Method of measurement
Visual Analog Scale (VAS), Neuropathic Pain Diagnostic Questionnaire along with blood tests and Quality Life Index for spinal cord injury

Intervention groups

1

Description
Intervention group 1: This Intervention group will receive BWSTT along with electrical stimulation (ES) and conventional physical therapy.
Category
Treatment - Devices

2

Description
Intervention group 2:This Intervention group will receive BWSTT and conventional physical therapy.
Category
Treatment - Devices

3

Description
Control group: This control group will receive conventional physical therapy only.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Paraplegic Center
Full name of responsible person
Dr. Amir Zeb
Street address
Sector P 1، Street 10, Phase 4
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Sponsors / Funding sources

1

Sponsor
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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
PhD sponsorship
Proportion provided by this source
80
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
Riphah College of Rehabilitation & Allied Health Sciences

Full name of responsible person
Dr. Amir Zeb

Position
PhD Scholar

Latest degree
Master

Other areas of specialty/work
Physiotherapy

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https://www.riphah.edu.pk/faculty-of-rehabilitation-and-allied-health-sciencesfrahs/

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Ethical concerns

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available