Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of task oriented functional and balance training on unsupported sitting balance in paraplegic patients

Protocol summary

Study aim
To determine the effect of task oriented functional and balance training for achieving unsupported sitting balance in paraplegic patients with fire arm injury

Design
Randomized Control Trial (RCT) Single blind study. Study groups: (task oriented) and (conventional exercises) group Phase: N.A Sample size : 30 Randomization: In this study simple random sampling technique is used by sealed envelop method through a computerized random number generator. The study is single blinded as participants is not aware of the intervention group they are placed in. Study center: Single center study

Settings and conduct
Paraplegic Centre Peshawar. Physiotherapy department. In this study simple random sampling technique is used by sealed envelop method by using a computerized random number generator. The study is single blinded as participants is not aware of the intervention group they are placed in.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age 17-60 Years, ASIA scoring A & B, Both Genders, Fire arm injury paraplegic patients (thoracic level), <6 months, able to sit supported on wheelchair for at least 30 minutes. Exclusion Criteria: External bracing or injuries affecting their ability to lift their arms above their head, existing stage 3 or 4 sacral pressure ulcer, chronic systemic diseases, Pregnant patients, extensive fixed contractures in the upper limbs.

Intervention groups
Two groups A and B. Group A experimental group (task oriented) and Group B control group (conventional exercises)

Main outcome variables
Sitting Balance Measure (SBM), Trunk control test, Goal Attainment scale (GAS) , Maximal lean test, Modified Functional Reach (mFR), Spinal cord injury falls efficacy scale (SCI-FES),SF-36

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211022052835N4**
Registration date: **2022-02-18, 1400/11/29**
Registration timing: **prospective**

Last update: **2022-02-18, 1400/11/29**
Update count: **0**

Registration date
2022-02-18, 1400/11/29

Registrant information

Name
Fouzia Batool
Name of organization / entity
Shifa Tameer-e-Millat University
Country
Pakistan
Phone
+92 51 8441752
Email address
fouzia_dpt.ahs@stmu.edu.pk

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-28, 1400/12/09

Expected recruitment end date
2022-05-30, 1401/03/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of task oriented functional and balance training on unsupported sitting balance in paraplegic patients

Public title
Effect of task oriented functional and balance training on unsupported sitting balance in paraplegic patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 17-60 years Both gender ASIA scoring A & B Fire arm injury paraplegic patients (thoracic level) Less than 6 months Patients who are able to sit supported on wheelchair for at least 30 minutes

Exclusion criteria:
Having external bracing or injuries affecting their ability to lift their arms above their head. Have an existing stage 3 or 4 sacral pressure ulcer according to the National Pressure Ulcer Advisory Panel classification Have chronic systemic diseases, e.g. hepatitis C or HIV-AIDS Pregnant patients Have extensive fixed contractures in the upper limbs

Age
From **17 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
An assessor-blinded, randomised controlled trial undertaken, in which participants with <6 months of spinal cord injury will be randomised to standard inpatient rehabilitation with additional task oriented training directed at improving their ability to sit unsupported. In this study simple random sampling technique is used by sealed envelop method by using a computerized random number generator. The sequence of random allocation is done by an individual who has not directly involved in the study. Random numbers is written on index cards and placed in thick and opaque sealed envelops before the study. After taking consent from the patient for their participation in the study, the therapist opens the envelop and give the respective treatments to the patients (Conventional Physical Therapy or Task Oriented Training) . The study is single blinded as participants is not aware of the intervention group they are placed in.

Blinding (investigator's opinion)
Single blinded

Blinding description
Prior to collecting data, participants would be informed about both the treatments and its benefits or risks. After taking informed consent, to avoid any kind of biasness, patient is asked to pick up one envelope. After that, the researcher doing the study knows which treatment or intervention the participant is receiving until the trial is over. The group A or B belongs to which way of treatment is known to therapist but the patient doesn't know about it. Participants are single blinded as they don't know which treatment plan or intervention is given to them.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Institutional review board and ethical committee shifa tameer-e-millat and shifa international hospi

Street address
Pitras Bukhari Road, Shifa international hospital Ltd. sector h-8/4 Islamabad

City
Islamabad

Postal code
44000

Approval date
2022-02-02, 1400/11/13

Ethics committee reference number
IRB#300-21

Health conditions studied

1

Description of health condition studied
only diagnosed paraplegic patients less than 6 months of spinal cord injury having limited function in unsupported sitting task oriented functional training

ICD-10 code
G82.2

ICD-10 code description
Paraplegia

Primary outcomes

1

Description
Balance training on unsupported sitting

Timepoint
Before intervention , after 4 weeks ,and 8 weeks after intervention.

Method of measurement
Sitting Balance Scale (SBS),Trunk control test, Maximal lean test, Modified Functional Reach (mFR)

Secondary outcomes

1

Description
Quality of life
Timepoint
Before intervention , after 4 weeks ,and 8 weeks after intervention.
Method of measurement
SF 36

2

Description
Fear of falling in unsupported sitting
Timepoint
Before intervention , after 4 weeks ,and 8 weeks after intervention.
Method of measurement
SCI-FCS

Intervention groups

1

Description
experimental group (task oriented) 30 minutes per session, 3 days per week, for 8 weeks. Task oriented functional training including Picking objects from floor, Reaching for objects, retrieve objects from counter, maintain orientation and apply force through object, picking up the coins, moving objects from one side of table to another
Category
Rehabilitation

2

Description
Control group: Progressive resistance training and functional strength training for 30 minutes per session, 3 days per week, for 8 weeks. Dosage for strengthening (progressive resistance training):one to three sets of 8-12 reps (rest 1-3mins between sets)2-3x per week. passive stretches, positioning in the lengthened position and other common hypertonic treatment techniques such as compression, heat and sustained deep pressure included.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Paraplegic Centre Peshawar
Full name of responsible person
Fariha Zulfiqar
Street address
Phase 4, Sector P 1, Street Number 10, Phase 4 Hayatabad, Peshawar, Khyber Pakhtunkhwa 25000
City
Peshawar
Postal code
25000
Phone
+92 91 9217902
Email
drfarihazulfiqar18@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shifa Tameer e Millat University Islamabad
Full name of responsible person
Fouzia Batool
Street address
Pitras Bukhari Road, Shifa Tameer-e-Millat University, H-8/4, Islamabad
City
Islamabad
Postal code
44000
Phone
+92 51 8441752
Email
fouzia_dpt.ahs@stmu.edu.pk
Web page address
https://stmu.edu.pk/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shifa Tameer e Millat University Islamabad
Proportion provided by this source
100
Public or private sector
Private
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
Shifa Tameer e Millat University Islamabad
Full name of responsible person
Fouzia Batool
Position
Assistant Professor
Latest degree

Master
Other areas of specialty/work
Physiotherapy
Street address
Pitras Bukhari Road, Shifa Tameer-e-Millat University, H-8/4, Islamabad
City
Islamabad
Province
Islamabad Capital Territory
Postal code
44000
Phone
+92 332 7120385
Email
fouzia_dpt.ahs@stmu.edu.pk

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shifa Tameer-e-Millat University
Full name of responsible person
Fouzia Batool
Position
Assistant Professor
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Pitras Bukhari Road, Shifa Tameer-e-Millat University, H-8/4, Islamabad
City
Islamabad
Province
Punjab
Postal code
44000
Phone
+92 332 7120385
Email
fouzia_dpt.ahs@stmu.edu.pk

Person responsible for updating data

Contact
Name of organization / entity
Shifa Tameer-e-Millat University
Full name of responsible person
Fouzia Batool
Position
Assistant Professor
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Pitras Bukhari Road, Shifa Tameer-e-Millat University, H-8/4, Islamabad
City
Islamabad
Province
Punjab
Postal code
44000
Phone
+92 51 8441752
Fax
Email
fouzia_dpt.ahs@stmu.edu.pk

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
There is no further information
Study Protocol
Yes - There is 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Effect of Task Oriented Functional & Balance Training for Achieving Unsupported Sitting Balance in Paraplegic Patients
When the data will become available and for how long
Data will not be available
To whom data/document is available
There is no such plan
Under which criteria data/document could be used
There is no such plan
From where data/document is obtainable
There is no such plan
What processes are involved for a request to access data/document
There is no such plan
Comments