

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 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 envelopes 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

drfari hazulfiqar18@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

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**Person responsible for scientific inquiries**

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**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**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**