

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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

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