

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

COMPARATIVE EFFECTS OF BACKWARD WALKING TRAINING AND STANDING BALANCE TRAINING ON WALKING SPEED AND BALANCE IN PATIENTS WITH SUBACUTE STROKE

Protocol summary

Study aim

To compare the effects of backward walking training and standing balance training in improving the walking speed & balance of the patients in the sub-acute phase of stroke rehabilitation.

Design

Single Blind, Randomized Controlled Clinical Trial

Settings and conduct

Madinah Teaching Hospital Faisalabad

Participants/Inclusion and exclusion criteria

Inclusion Criteria 1. Diagnosis of first stroke in previous 45 days, 2. Patients older than 20 years and less than 50 years, 3. Able to maintain upright standing posture with moderate assistance, 4. Anticipated inpatient rehabilitation length of stay 2 to 3 weeks, Exclusion Criteria 1. Absence of significant balance impairment, defined by Berg Balance Scale (BBS) score greater than 45/56, 2. Lower extremity joint or weight-bearing pain, 3. Inability to follow 2-step command, 4. History of Contraversive pushing syndrome

Intervention groups

Group A: Group A participants received the task-oriented training (grasping objects and CIMT) combined with backward walking training. The participants were treated 60 minutes, 3 times per week for 4 weeks. Group B: Group B participants received the task-oriented training (grasping objects and CIMT) combined with standing balance training. The participants were treated 60 minutes, 3 times per week for 4 weeks.

Main outcome variables

• 6-Meter walk test • 3-meter backward walk test • Berg balance scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210507051205N1**

Registration date: **2021-09-15, 1400/06/24**

Registration timing: **retrospective**

Last update: **2021-09-15, 1400/06/24**

Update count: **0**

Registration date

2021-09-15, 1400/06/24

Registrant information

Name

Muhammad Umer Shabbir

Name of organization / entity

The University of Faisalabad

Country

Pakistan

Phone

+92 41 8750971

Email address

muhammad.umer.shabbir@tuf.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-02, 1399/05/12

Expected recruitment end date

2021-05-15, 1400/02/25

Actual recruitment start date

2020-08-04, 1399/05/14

Actual recruitment end date

2021-04-05, 1400/01/16

Trial completion date

2021-07-30, 1400/05/08

Scientific title

COMPARATIVE EFFECTS OF BACKWARD WALKING

TRAINING AND STANDING BALANCE TRAINING ON WALKING SPEED AND BALANCE IN PATIENTS WITH SUBACUTE STROKE

Public title

COMPARATIVE EFFECTS OF BACKWARD WALKING TRAINING AND STANDING BALANCE TRAINING ON WALKING SPEED AND BALANCE IN PATIENTS WITH SUBACUTE STROKE

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of first stroke in previous 45 days, Patients older than 20 years and less than 50 years, Able to maintain upright standing posture with moderate assistance, Anticipated inpatient rehabilitation length of stay 2 to 3 weeks, Anticipated remaining in the geographic area for the study duration, Vision within functional limits (considered enough for gait training)

Exclusion criteria:

Absence of significant balance impairment, defined by Berg Balance Scale (BBS) score greater than 45/56, Lower extremity joint or weight-bearing pain, Other neurological diagnoses, Inability to follow 2-step command, History of Contraversive pushing syndrome, History of Cerebellar stroke.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **61**

Actual sample size reached: **61**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done using an online random number generator, randomizer.org. Website determined 2 sets (A and B). Set A was BWT group and set B was SBT group. The numbers from 1-70 were selected (The sample size was 70, 35 in each group). Randomizer generated the numbers for each group (A or B) and patients were allocated based on that numbers.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants had no information about the treatment given in both groups

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

UIPT Ethical Review Committee

Street address

Defense road bhuptian chowk

City

Lahore

Postal code

3800

Approval date

2020-07-29, 1399/05/08

Ethics committee reference number

IRB-UOL-FAHS/740-V/2020

Health conditions studied

1

Description of health condition studied

Subacute Stroke

ICD-10 code

I69.869

ICD-10 code description

Other paralytic syndrome following other cerebrovascular disease affecting unspecified side

Primary outcomes

1

Description

Berg balance scale

Timepoint

baseline, after 3 weeks and at the end of 6th week

Method of measurement

The 14-item scale was used to assess the static and dynamic standing balance, sitting, standing up, and transfer ability. This scale has a great reliability, validity and it has been in use for years for assessing the balance in post-stroke patients.

Secondary outcomes

1

Description

6-Meter walk test

Timepoint

at baseline, at the end of 2nd week and at the end of 4th week

Method of measurement

The 6-Meter Walk Test was used to evaluate gait speed, which helped to explain responsiveness in stroke patients. A stopwatch was used to record the amount of

time it took to walk. Participants covered the distance twice at their own pace to determine their average gait speed. If balance aid was needed, it was given, but no help with the lower extremities was offered. At each research time point, the evaluation was performed with the least orthotic and restrictive assistive device possible.

2

Description

3-meter backward walk test

Timepoint

at baseline, at the end of 2nd week and at the end of 4th week

Method of measurement

The 3-Meter Backward Walk Test was used to determine backward walking speed. A timer was used to record the time it took to walk backward 3 meters. Participants covered the distance twice at their own pace to determine their average gait speed. If balance aid was needed, it was given, but no help with the lower extremities was offered. At each research time point, the evaluation was performed using the least orthotic and restrictive assistive device.

3

Description

Berg balance scale

Timepoint

at baseline, at the end of 2nd week and at the end of 4th week

Method of measurement

This 14-item scale assessed the static and dynamic standing balance, sitting, standing up, and transfer ability. This scale has a great reliability, validity and it has been in use for years for assessing the balance in post-stroke patients. This scale measured the questions on the basis of Likert scale system and the score ranged from 0-56 and the scoring reference is as: 41-56 = independent 21-40 = walking with assistance 0 -20 = wheelchair bound

Intervention groups

1

Description

Intervention group: Group A: Group A participants received the task oriented training (grasping objects and CIMT) combined with backward walking training. The participants were treated 60 minutes, 3 times per week for 4 weeks.

Category

Rehabilitation

2

Description

Intervention group: Group B: Group B participants received the task oriented training (grasping objects and CIMT) combined with standing balance training. The

participants were treated 60 minutes, 3 times per week for 4 weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Madinah Teaching Hospital

Full name of responsible person

Dr. Mohsin Hussain PT

Street address

Sargodha Road Faisalabad

City

Faisalabad

Postal code

38000

Phone

+92 41 8750971

Email

M.mohsinhussain@tuf.edu.pk

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Madinah Teaching Hospital Faisalabad

Full name of responsible person

Dr. Mohsin Hussain PT

Street address

Sargodha Road Faisalabad

City

Faisalabad

Postal code

38000

Phone

+92 41 8750971

Email

m.mohsinhussain@tuf.edu.pk

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

N/A

Proportion provided by this source

1

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

The University of Faisalabad

Full name of responsible person

Muhammad Umer Shabbir

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Neurology

Street address

West canal road faisal town

City

Faisalabad

Province

Punjab

Postal code

38000

Phone

+92 41 8750971

Email

muhammad.umer.shabbir@tuf.edu.pk

Person responsible for scientific inquiries

Contact

Name of organization / entity

The University of Faisalabad

Full name of responsible person

Dr. Mohsin Hussain PT

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

West canal road faisal town

City

Faisalabad

Province

Punjab

Postal code

38000

Phone

+92 41 8750971

Email

m.mohsinhussain@tuf.edu.pk

Person responsible for updating data

Contact

Name of organization / entity

The University of Faisalabad

Full name of responsible person

Muhammad Umer Shabbir

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Neurology

Street address

West canal road faisal town

City

Faisalabad

Province

Punjab

Postal code

38000

Phone

+92 41 8750971

Email

muhammad.umer.shabbir@tuf.edu.pk

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The primary and secondary outcome measure data will be shared and no further detail regarding patients personal information will be provided

When the data will become available and for how long

Starting in January 2022

To whom data/document is available

Researchers , scholars, physiotherapist

Under which criteria data/document could be used

none

From where data/document is obtainable

Direct contact with Responsible

What processes are involved for a request to access data/document

Access as per policy

Comments

none