Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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
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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
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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
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
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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