

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### The effects of Theraband-assisted treadmill training on balance and gait outcomes in stroke patients: A randomised controlled trial

#### Protocol summary

##### Study aim

To determine the effects of Theraband assisted treadmill training on GAIT and balance outcomes in stroke patients

##### Design

single blinded, parallel group, randomized controlled trial

##### Settings and conduct

Post-stroke patients referred to the Rehman Medical Institute, Peshawar, during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through block randomization. This trial will be single-blinded so that the outcome assessor does not know about the intervention group.

##### Participants/Inclusion and exclusion criteria

Inclusion: Stroke onset >6 months, Age 30-65 years.

Exclusion: Recurrent strokes more than twice

##### Intervention groups

Experimental group: • A total of 50 minutes of training will be given, which will include Treadmill training with theraband for 30 minutes in a harness support and conventional therapy (general stretching and strengthening exercises) for 20 minutes, 5 days a week, for a total of 4 weeks. • 30 minutes treadmill training will be given in three sets of 10 minutes each. with 2 minutes of rest in between. • Participants will walk on a treadmill at a normal pace. Speed for the first 2 weeks will be 1m/s and of the last 2 weeks will be 1.5m/s. Control group: • A total of 50 minutes of training will be given, which will include Treadmill training for 30 minutes in a harness support and conventional therapy (general stretching and strengthening). exercises) for 20 minutes, 5 days a week, for a total of 4 weeks. • 30 minutes treadmill training will be given in three sets of 10 minutes each. with 2 minutes of rest in between. • Participants will walk on a treadmill at a normal pace. Speed for the first 2 weeks will be 1m/s and of the last 2 weeks will be 1.5 m/s.

##### Main outcome variables

Balance, Gait

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230615058491N1**

Registration date: **2023-11-12, 1402/08/21**

Registration timing: **retrospective**

Last update: **2023-11-12, 1402/08/21**

Update count: **0**

##### Registration date

2023-11-12, 1402/08/21

##### Registrant information

##### Name

Maaham Ali

##### Name of organization / entity

Khyber medical university

##### Country

Pakistan

##### Phone

+92 336 8830999

##### Email address

maahamali99@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-18, 1402/06/27

##### Expected recruitment end date

2023-09-18, 1402/06/27

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The effects of Theraband-assisted treadmill training on balance and gait outcomes in stroke patients: A randomised controlled trial

## Public title

Effects of Theraband-assisted training on balance and gait outcomes in stroke patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Stroke onset greater than 6 months. Age between 30-65yrs. Ability to follow one step command, MMSE scores  $\geq 24$ . Ability to walk independently or with assistive device. Participants who are interested and able to take part in a supervised rehabilitation program for at least 4 weeks.

### Exclusion criteria:

More than one hemisphere involved. Recurrent strokes greater than two. Participants with any diagnosed cardiovascular illness or diabetic neuropathy. Participants with any diagnosed neurological or musculoskeletal problems, other than stroke, that impact their gait or balance. Participants who currently have or have previously had any diagnosed vestibular problems. Having any diagnosed significant lower limb abnormalities (e.g. clubfoot, polio, foot drop, fractures).

## Age

From **30 years** old to **65 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Outcome assessor

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In our trial, randomization will be conducted using a sealed envelope method. The unit of randomization is the individual participant. For each participant, a unique identifier will be assigned, and these identifiers will be placed in separate, opaque, and sealed envelopes. The envelopes will be thoroughly mixed before a neutral third party, who is not involved in the trial, draws an envelope for each participant. The treatment assignment corresponding to the label inside the drawn envelope will determine whether the participant receives Theraband-assisted treadmill training or standard treadmill training. This method ensures the transparency and fairness of the allocation process, eliminating any potential for selection bias. Allocation concealment will be maintained throughout the trial, as the envelopes will be securely stored and opened only at the time of participant allocation

## Blinding (investigator's opinion)

Single blinded

## Blinding description

One physical therapist will provide the treatment session, another physical therapist will assess the pre and post Tx outcomes of the patients from both groups, outcomes assessor will be blinded in this study.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

### 1

#### Registry name

#### Secondary trial Id

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

KMU AS&RB

##### Street address

Hayatabad phase 5

##### City

Peshawar

##### Postal code

25100

#### Approval date

2023-09-04, 1402/06/13

#### Ethics committee reference number

KMU/MSPT/NMPT/2023/1

## Health conditions studied

### 1

#### Description of health condition studied

Stroke

#### ICD-10 code

G46.4

#### ICD-10 code description

Cerebellar stroke syndrome

## Primary outcomes

### 1

#### Description

GAIT

#### Timepoint

Before intervention as a baseline and then at the end of intervention after 4 weeks

#### Method of measurement

10 meter walk test will be used to assess the GAIT outcome of patient. A stopwatch and a 10 m pathway will be required for the test. A score of  $<0.4$ m/s shows

household ambulation, 0.4-0.8m/s shows limited community ambulation and >0.8m/s shows community ambulation.

## 2

### **Description**

Balance

### **Timepoint**

Before intervention as a baseline and then at the end of intervention after 4 weeks

### **Method of measurement**

Functional reach test will be used to assess the balance of the participants. It will need measuring tape on the wall and patient will lean forward and score will be noted. A score of greater than 25 will be considered low risk, 15-25 moderate risk and less than 15 high risk of fall.

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: • A total of 50 minutes session will be given which will include Treadmill training with theraband for 30 minutes in a harness support and conventional therapy (general stretching & strengthening exercises) for 20 minutes, 5 days a week for a total of 4 weeks. • 30 minutes treadmill training will be given in three sets each of 10 minutes (8 minutes training with 2 minutes rest in between). • Participants will walk on treadmill at a normal pace. Speed for the first 2 weeks will be 1m/s and of the last 2 weeks will be 1.5m/s. • Two theraband will be used, green color theraband will be used to assist dorsiflexion, while the black theraband will be tied to an abdominal belt crossing in front of the ankle, back of the knee and front of the hip joint.

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: • A total of 50 minutes session will be given which will include Treadmill training for 30 minutes in a harness support and conventional therapy (general stretching & strengthening exercises) for 20 minutes, 5 days a week for a total of 4 weeks. • 30 minutes treadmill training will be given in three sets each of 10 minutes (8 minutes training with 2 minutes rest in between). • Participants will walk on treadmill at a normal pace. Speed for the first 2 weeks will be 1m/s and of the last 2 weeks will be 1.5m/s.

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Rehman Medical Institute (RMI)

##### **Full name of responsible person**

Maaham Ali

##### **Street address**

5-B/2 Shaukat Khanum Rd, Phase 5 Hayatabad, Peshawar, Khyber Pakhtunkhwa

##### **City**

Peshawar

##### **Postal code**

25000

##### **Phone**

+92 91 5838000

##### **Email**

info@rmi.edu.pk

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Rehman Medical Institute RMI

##### **Full name of responsible person**

Maaham Ali

##### **Street address**

5-B/2 Shaukat Khanum Rd, Phase 5 Hayatabad, Peshawar, Khyber Pakhtunkhwa

##### **City**

Peshawar

##### **Postal code**

25000

##### **Phone**

+92 336 8830999

##### **Email**

info@rmi.edu.pk

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Rehman Medical Institute RMI

#### **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**

Khyber medical university

**Full name of responsible person**

Maaham Ali

**Position**

Post graduate student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

5-B/2 Shaukat Khanum Rd, Phase 5 Hayatabad,  
Peshawar, Khyber Pakhtunkhwa

**City**

Peshwar

**Province**

Khyber pakhtunkhwa

**Postal code**

25000

**Phone**

+92 336 8830999

**Email**

maahamali99@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Khyber medical university

**Full name of responsible person**

Maaham Ali

**Position**

Post graduate student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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Khyber medical university

**Full name of responsible person**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Primary outcomes data

**When the data will become available and for how long**

Data will be available in January 2024 for two years

**To whom data/document is available**

All the students, teachers and research scholars

**Under which criteria data/document could be used**

The person will have to email the principal investigator for data

**From where data/document is obtainable**

From Principal investigator

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

Through mail communication with author

**Comments**