

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 ≥ 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,
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City

Peshwar

Province

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Postal code

25000

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+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

Physiotherapy

Street address

5-B/2 Shaukat Khanum Rd, Phase 5 Hayatabad,
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City

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25000

Phone

+92 336 8830999

Email

maahamali99@gmail.com

Person responsible for updating data

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

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Email

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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