Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 envolpe 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 <0.4m/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
Physiotherapy

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City
Peshawar

Province
Khyberpakhtunkhwa

Postal code
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

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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 availabe in January 2024 for two years

To whom data/document is available
All the students, teachers and resreach 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 Prinicapal investigator

What processes are involved for a request to access data/document
Through mail communication with author

Comments