

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of Task-Oriented Circuit Training and Vestibular Rehabilitation Therapy on Balance, Gait and fear of falling in Elderly population.

Protocol summary

Study aim

To compare the effects of Vestibular Rehabilitation Therapy and Task-Oriented Circuit Training on Gait, Balance and fear of falling in Elderly Population.

Design

Randomized Clinical Trial

Settings and conduct

Allied Hospital Faisalabad- Old Age Shelter Home
Faisalabad

Participants/Inclusion and exclusion criteria

Inclusion criteria: age of participants 60 y/o or more; have fallen at least once in the last 12 months; taking more than 15 s in the timed up-and-go (TUG) test; both genders; identified as medium fall risk on BBS (21-40)/56. Exclusion criteria: balance disorders(neurologic, vestibular, etc.); organic conditions.

Intervention groups

Task-Oriented Circuit Training: The protocol will included: Sit to stand, Stand up and walk (6 m),Walking over inclined surface (3 m), Step, Taking an object from the ground while walking (6 m), Slalom (6 m),Climb and descend stairs, Touch different point marked a semicircle on a mirror with the feet, Reaching to object while standing, Standing on a movable platform Vestibular Rehabilitation Therapy: Head movement: backward and forward bending, turning from right to left, Balancing on a mat and swiveling eyes, Standing on a sports mat, walking on the spot, and rotating the head on both sides, Alternately shift weight toward one limb while maintaining partial weight bearing on the other, keeping the sight on a fixed target object. Repeated for the opposite side, Standing on foam with closed eyes and rotating the head on both sides, Forward and backward walking with a side-to-side head turn, Sitting on a ball with feet on foam, eyes closed, and bouncing slightly while turning the head from side to side, Marching in place. The sessions will be 20 to 30 minutes; 3 days per

week for 6 weeks.

Main outcome variables

Timed Up-and-Go (TUG) Test; Dynamic Gait Index; Falls Efficacy Scale-International(FES-I)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230608058418N1**

Registration date: **2023-07-18, 1402/04/27**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-18, 1402/04/27**

Update count: **0**

Registration date

2023-07-18, 1402/04/27

Registrant information

Name

Vishal Sana

Name of organization / entity

Riphah international university

Country

Pakistan

Phone

+92 41 8777210

Email address

draqsabashir117@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-27, 1402/04/06

Expected recruitment end date

2023-10-27, 1402/08/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Task-Oriented Circuit Training and Vestibular Rehabilitation Therapy on Balance, Gait and fear of falling in Elderly population.

Public title

Comparison of Task-Oriented Circuit Training and Vestibular Rehabilitation Therapy on Balance, Gait and fear of falling in Elderly population.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of participants 60 or more Have fallen at least once in the last 12 months Taking more than 15 s, or needing support, in the timed up-and-go (TUG) test Both genders Identified as medium fall risk on BBS (21-40)/56

Exclusion criteria:

Cognitive decline that prevents the patient from understanding the assessment, vestibular rehabilitation exercises, and granting informed consent Balance disorders caused by conditions other than age (neurologic, vestibular, etc.) Organic conditions that prevent standing on two feet, which is necessary for a complete postural assessment and performance of vestibular rehabilitation exercises.

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization will be done by Random Allocation Software version 2. Participants will be divided into two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The Blinding will done by blinding the outcome accessor because Outcome accessor and Researcher will two different persons.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research and Ethical Committee

Street address

Adjacent Fish Farm, Satayana Rd, Faisalabad, Punjab

City

Faisalabad

Postal code

38000

Approval date

2023-06-28, 1402/04/07

Ethics committee reference number

REC-FSD-00319

Health conditions studied**1****Description of health condition studied**

Gait

ICD-10 code

R26

ICD-10 code description

Gait

Primary outcomes**1****Description**

Balance

Timepoint

Before Intervention and 6 weeks after intervention.

Method of measurement

Timed Up-and-Go (TUG) Test

2**Description**

Gait

Timepoint

Before Intervention and 6 weeks after intervention.

Method of measurement

Dynamic Gait Index

3**Description**

Fear of falling

Timepoint

Before Intervention and 6 weeks after intervention.

Method of measurement

Falls Efficacy Scale-International (FES-I)

Secondary outcomes

empty

Intervention groups

1

Description

Task-Oriented Circuit Training is a useful approach to improve balance and gait function for those having a fear of falling and abnormal gait pattern. The TOCT is based on workstations including different motor tasks related to daily living activities such as maintaining balance, walking, and reaching. TOCT may allow a more intensive (more repetitions) and specific (task-oriented) exercise in a developed rehabilitative setting. It has positive effects on gait and fall-related injuries which is more common in elderly population

Category

Treatment - Other

2

Description

Vestibular Rehabilitation Therapy is exercise-based program that has been around for more than 70 years. Patients with gait issues can benefit from a form of treatment that is vestibular rehabilitation. Vestibular rehabilitation improves static and dynamic balance stability. It improves gait parameters in elderly patients, allowing patients to walk more securely and direct more easily during walking

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Allied Hospital Faisalabad

Full name of responsible person

Dr. Sobia Nawaz

Street address

Dr. Tusi Rd, Faisalabad, Punjab

City

Faisalabad

Postal code

38000

Phone

+92 334 8196967

Email

info@pmc.edu.pk

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Riphah International University Faisalabad

Full name of responsible person

Dr Sahreen

Street address

Adjacent Fish Farm, Satayana Rd, Faisalabad, Punjab

City

Faisalabad

Postal code

38000

Phone

+92 41 8777210

Email

contact@riphahfsd.edu.pk

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Riphah International University Faisalabad

Proportion provided by this source

10

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

Riphah International University Faisalabad

Full name of responsible person

Dr Vishal Sana

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

House#P44, Usman colony near Allied moor, Faisalabad

City

Faisalabad

Province

Punjab

Postal code

38000

Phone

+92 348 6665054

Email

vishsana24@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Riphah International University Faisalabad

Full name of responsible person

Dr. Vishal Sana

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Sharing IPD may raise privacy and confidentiality concerns, especially when the data contains sensitive or personally identifiable information. There may be legal or ethical obligations to protect the privacy of the participants, and sharing their data could violate those obligations.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The data set of IPD will be shared for primary outcomes only.

When the data will become available and for how long

Starting in October 2023

To whom data/document is available

Data set will be available for academic persons.

Under which criteria data/document could be used

The documents will be used for further research purposes.

From where data/document is obtainable

The data will be provided from email Id
vishsana24@gmail.com

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

The applicant should send a email for requesting the documents and request will be followed within 72 hours.

Comments