Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative effects of aerobic training and circuit training on balance and disease severity in ataxic patients

Protocol summary

Study aim
To determine the individual effects of aerobic training and circuit training and comparison of these two on balance and disease severity in ataxic patients.

Design
Randomized clinical trial, parallel group, single-blinded study.

Settings and conduct
The setting of this study is Allied Hospital, Faisalabad. It is a single blinded study in which participants will be blinded. They will be allocated into the groups through online randomization generator.

Participants/Inclusion and exclusion criteria
Inclusion Criteria • Participants ranging from 30-65 years of age were included in this study (mid adulthood). • Scale for Assessment and Rating of Ataxia (SARA) sitting sub-score was less than or equal to 1 (patients are able to sit and use a stationary exercise bike). • Both genders were included in this study. • Hemodynamically stable patients. • Patient fall on stage “3 and 4” of Ataxia staging scale. • Patients were able to walk independently with or without assistive device for at least 5 minutes (as a minimum criteria). Exclusion Criteria • Patient suffering from recent surgery of low back or lower limb. • Patient encountered any recent musculoskeletal injury (fracture, dislocation, soft tissue injury). • Patients suffering from heart problems/diseases. • Patients who were unable to exercise. • Medically unstable patients. • Uncooperative patients

Intervention groups
Group 1is Aerobic training group (30 minutes on stationary cycling) Group 2 is Circuit training group (Stretching of calf and hams (30 sec hold/5 rep), bridging (1 set/5 rep), sit to stand (1 set/5 rep 30 seconds standing in each rep), stationary cycling (5 minute) and walk on parallel bars (5 minute)

Main outcome variables
• Disease severity of ataxic patients is the primary outcome of this study. • Balance is the secondary outcome of this study.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240323061354N1**
Registration date: **2024-05-02, 1403/02/13**
Registration timing: **prospective**

Last update: **2024-05-02, 1403/02/13**
Update count: **0**

Registration date
2024-05-02, 1403/02/13

Registrant information

Name
Hifza Ahmed

Name of organization / entity
The University of Faisalabad

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Pakistan

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-03, 1403/02/14

Expected recruitment end date
2024-09-02, 1403/06/12

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative effects of aerobic training and circuit training on balance and disease severity in ataxic patients

Public title
Comparative effects of aerobic training and circuit training on balance and disease severity in ataxic patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Participants ranging from 30-65 years of age were included in this study (mid adulthood). Scale for Assessment and Rating of Ataxia (SARA) sitting sub-score was less than or equal to 1 (patients are able to sit and use a stationary exercise bike). Hemodynamically stable patients. Patient fall on stage “3 and 4” of Ataxia staging scale. Patients were able to walk independently with or without assistive device for at least 5 minutes (as a minimum criteria). Diagnosed ataxic patients

Exclusion criteria:
Patient suffering from recent surgery of low back or lower limb. Patient encountered any recent musculoskeletal injury (fracture, dislocation, soft tissue injury) Patients suffering from heart problems/diseases. Patients who were unable to exercise. Medically unstable patients. Uncooperative patients

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

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple random sampling was used to allocate patients. The allocation of the participants was done using lottery method. According to that patients were assigned into group 1 and group 2.

Blinding (investigator's opinion)
Single blinded

Blinding description
The participants will be blinded in this study as they will be allocated into groups through the use of lottery method. After carefully selecting individuals for this study, a box will be prepared with the folded chits in it. Those chits will have the names of the participants. Afterwards, a third person (random person) will be asked to draw those chits. The odd number chits will be added in the first treatment group (aerobic training group) and the chits that will be drawn at the even number, added in the second treatment group (circuit training group).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research and Ethics/ Technical Committee for the University of Faisalabad

Street address
University Avenue, Faisal town, Canal road, Faisalabad.

City
Faisalabad

Postal code
38000

Approval date
2024-02-17, 1402/11/28

Ethics committee reference number
TUF/DR/SA/MSPP/2024/395

Health conditions studied

1

Description of health condition studied
Ataxia due to cerebellar atrophy or degeneration, stroke and multiple sclerosis.

ICD-10 code
G32.81, G3

ICD-10 code description
Cerebellar ataxia in diseases classified elsewhere, Multiple Sclerosis

Primary outcomes

1

Description
Disease severity in ataxia

Timepoint
Before intervention and at the end of 4 weeks of intervention.

Method of measurement
Scale for Assessment and Rating of Ataxia (SARA)

Secondary outcomes

1

Description

Balance

Timepoint

Before intervention and at the end of 4 weeks of intervention.

Method of measurement

Berg balance scale (BBS)

2

Description

Ataxia Staging

Timepoint

Before intervention and at the end of 4 weeks of intervention.

Method of measurement

Functional Staging for Ataxia

Intervention groups

1

Description

Intervention group 1: Aerobic training group (using stationary cycle for 30 minutes duration)

Category

Treatment - Devices

2

Description

Intervention group 2: Circuit training group. Combination of exercises (Stretching of calf and hams (30 sec hold/5 rep), bridging (1 set/5 rep), sit to stand (1 set/5 rep 30 seconds standing in each rep), stationary cycling (5 minute) and walk on parallel bars (5 minute)

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Allied Hospital, Faisalabad.

Full name of responsible person

Sobia Nawaz

Street address

Dr. Tusi Road, Faisalabad.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Faisalabad

Full name of responsible person

Nisar Fatima

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Sargodha Rd, University Town, Faisalabad.

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nisar.fatima@tuf.edu.pk

Web page address

https://tuf.edu.pk/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

The University of Faisalabad

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

The University of Faisalabad

Full name of responsible person

Hifza Ahmed

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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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
No - There is not 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
Comparative effects of aerobic training and circuit training on balance and disease severity in ataxic patients
When the data will become available and for how long
Sharing six months after publication and it will remain available for everyone
To whom data/document is available
This will be available for everyone
Under which criteria data/document could be used
nisar.fatima@tuf.edu.pk (0092 331 8711448)
From where data/document is obtainable
hifzaahmed77@gmail.com (0092 304 6887080)
What processes are involved for a request to access data/document
Any applicant just need to contact at email hifzaahmed77@gmail.com (0092 304 6887080) for data/documents.
Comments