

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 1 is 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

Country

Pakistan

Phone

+92 41 2630517

Email address

hifzashams29@gmail.com

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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sobiaaliawan@gmail.com
Web page address
<https://ahfsd.pk/>

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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Postal code
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Phone
+92 331 8711448
Email
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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Person responsible for updating data

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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