

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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

2022-ms-pt-030@tuf.edu.pk

##### 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.  
**City**  
Faisalabad  
**Postal code**  
38000  
**Phone**  
+92 321 7665101  
**Email**  
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  
**Street address**  
Sargodha Rd, University Town, Faisalabad.  
**City**  
Faisalabad  
**Postal code**  
38000  
**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  
**Street address**  
No. 67b Umer Block, Gulshan e Madina Phase 1, Sargodha Rd, Faisalabad  
**City**  
Faisalabad  
**Province**  
Punjab  
**Postal code**  
38000

**Phone**  
+92 41 2630517  
**Email**  
hifzaahmed77@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
The University of Faisalabad  
**Full name of responsible person**  
Hifza Ahmed  
**Position**  
Student  
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**Other areas of specialty/work**  
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**Street address**  
No. 67b Umer Block, Gulshan e Madina Phase 1,  
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Punjab  
**Postal code**  
38000  
**Phone**  
+92 41 2630517  
**Email**  
2022-ms-pt-030@tuf.edu.pk

## Person responsible for updating data

### Contact

**Name of organization / entity**  
The University of Faisalabad  
**Full name of responsible person**  
Hifza Ahmed  
**Position**  
Student  
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hifzaahmed77@gmail.com

## 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