

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the Effectiveness of Aerobic Training with Conventional Physical Therapy Treatment in improving the quality of life in Chronic Stroke Patient

#### Protocol summary

##### Study aim

this study aim is to compare the effects of Aerobic Exercise (Walking) Training and conventional physical therapy treatment in improving the quality of life in Chronic Stroke patient

##### Design

two study group were made after taking the sample size of 60 by using the epitool website to online calculate the sample size and then divide into two groups. The sample was recruited through convenient sampling technique and then randomly assigned to the two groups. this will be single blinded study (assessor blind).

##### Settings and conduct

Data was collected from following settings, • Haq orthopedic hospital sanda road lahore • Hijaz hospital gulberg lahore • Chudhary Muhammad teaching hospital lahore • Journal hospita our trial is single blind in which we have used the assor blind technique through which the person who is taking the assesment after the treatment protocol is unaware

##### Participants/Inclusion and exclusion criteria

Inclusion criteria • Age 45-75years. • Patients both Genders. • Chronic stroke • Lower limb should be functional atleast upto grade • Walking independently with or without of an assistive device Exclusion criteria • Stroke due to subarachnoid hemorrhage • Patients with any Systemic Illness(e.g. Rheumatism) • Patient with Mental disability

##### Intervention groups

. Then participants were randomly divided into two groups. Interventional group : In group-A participants were given aerobic training (n=30) 30 minutes walk, 3 times a week for 12 weeks. Group-B participants were given conventional physical therapy including stretching and strengthening with massage to involved limb For 30 minutes, 3 times a week for 12 weeks They were tested before and after treatment session by using the outcome

measuring tool morticity index and SF-36( HR-QOL)

##### Main outcome variables

Quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210614051572N1**

Registration date: **2022-06-15, 1401/03/25**

Registration timing: **retrospective**

Last update: **2022-06-15, 1401/03/25**

Update count: **0**

##### Registration date

2022-06-15, 1401/03/25

##### Registrant information

##### Name

gulnaz zaheer

##### Name of organization / entity

The superior university lahore pakistan

##### Country

Pakistan

##### Phone

+92 42 35244954

##### Email address

zaheergulnaz4@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-01-28, 1400/11/08

##### Expected recruitment end date

2022-02-28, 1400/12/09

##### Actual recruitment start date

2022-03-05, 1400/12/14  
**Actual recruitment end date**  
2022-03-07, 1400/12/16  
**Trial completion date**  
2022-05-28, 1401/03/07

**Scientific title**  
Comparison of the Effectiveness of Aerobic Training with Conventional Physical Therapy Treatment in improving the quality of life in Chronic Stroke Patient

**Public title**  
Effects of Aerobic Training with Conventional Physical Therapy Treatment in Chronic Stroke Patient

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

• Age 45-75years • Patients from both Genders • Patient with Chronic stroke • Lower limb should be functional atleast upto grade 1 • Walking independently with or without of an assistive device

**Exclusion criteria:**

• Stroke due to subarachnoid hemorrhage • Stroke due to subarachnoid hemorrhage • Patients with lethargy obturant • Patient with Mental disability

**Age**

From **45 years** old to **75 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Participants who fulfilled the inclusion criteria were selected convenient sampling technique and were then allocated randomly to Group A and Group B using lottery method. This distribution process is hidden between participants and researchers. This was done by a research assistant who did not participate in any further research.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

the assesor of the study is blind he will not know about the treatment protocol is given to participant and from which group the belongs

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Sample size was calculated using data from previous studies, Health-related quality of life of SF-36 was used as a measure of outcome tool with  $\mu_1 - \mu_2$  and  $\sigma_1^2 + \sigma_2^2$

$n = (Z_{1-\beta} + Z_{\alpha/2})^2 (\sigma_1^2 + \sigma_2^2) (\mu_1 - \mu_2)^2$  Estimated  
Sample size was 60

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Azra naheed centre for research and development  
Ethical Committee

**Street address**

17-km riwind road ,Lahore

**City**

Lahore

**Postal code**

54000

**Approval date**

2022-02-21, 1400/12/02

**Ethics committee reference number**

SU/ANCRD/IERC/55

## Health conditions studied

### 1

**Description of health condition studied**

Arterial occlusion (stroke) results in infarction of brain in the distribution of that vessel. Brain infarct can be plain (80%) or hemorrhagic (20%)

**ICD-10 code**

163.9

**ICD-10 code description**

chronic stroke

## Primary outcomes

### 1

**Description**

quality of life

**Timepoint**

befre and after the 12 weeks of treatment

**Method of measurement**

Health related quality of life Sf-36

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Interventional Group: aerobic training walking (n=30) 30 minutes walk, 3 times a week for 12 weeks for improving mortality index and health related quality of life

**Category**

Rehabilitation

2**Description**

Control group: Control group:conventional physical therapy including stretching and strengthening with massage to involved limb (n=30) to improve mortality index and health related quality of life

**Category**

Rehabilitation

**Recruitment centers**1**Recruitment center****Name of recruitment center**

Chudhary Muhammad Akram teaching hospital lahore

**Full name of responsible person**

Dr zohaib

**Street address**

17 km riwind road Lahore

**City**

Lahore

**Postal code**

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**Phone**

+92 333 6979114

**Email**

zohaib.rana@superior.edu.pk

**Web page address**

<https://www.facebook.com/Doctor-of-Physical-Therapy-Azra-Naheed-Medical-CollegeSuperior-University-144600035742592>

**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

The Superior University

**Full name of responsible person**

Gulnaz Yamin

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**Phone**

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**Email**

zohaib.rana@superior.edu.pk

**Web page address**<https://www.superior.edu.pk/>**Grant name**

no

**Grant code / Reference number**

no

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

No

**Title of funding source**

no

**Proportion provided by this source**

1

**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**

Other

**Person responsible for general inquiries****Contact****Name of organization / entity**

The superior University

**Full name of responsible person**

Gulnaz Yamin

**Position**

Assistant Professor

**Latest degree**

Master

**Other areas of specialty/work**

Rehabilitation management

**Street address**

17 km riwind road Lahore

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**Province**

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**Postal code**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

The Superior University

**Full name of responsible person**

Gulnaz Yamin

**Position**

Assistant Professor

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

17 kn riwind road Lahore

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University-144600035742592

## 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**

All data after de-identification will be shared

**When the data will become available and for how long**

When the trial has been completed after the end of August 2022 the data will be available for the future use and after the completion of trial when it get published approximately after 4 weeks in the start of october 2022 and the summry data will be available after the article get published

**To whom data/document is available**

It will be available to all Teaching institute and hospital for the better cure of the patient.more over it will available for the researcher as well

**Under which criteria data/document could be used**

Only for the research and for the benefits of public

**From where data/document is obtainable**

the document will be available on the following details email: zaheergulnaz4@gmail.com contact no :03244694034 postal address:Department of physicaltherapy The Superior University, 17 km riwid road ,Lahore

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

application sent on email on request zaheergulnaz4@gmail.com

**Comments**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

The Superior University

**Full name of responsible person**

Gulnaz Yamin

**Position**

Assistant Professor

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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