

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 hospital our trial is single blind in which we have used the assessor blind technique through which the person who is taking the assessment 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 mortality 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 morticity index and health realted 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 morticity index and health related quality of life

Category

Rehabilitation

Recruitment centers1**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

54000

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 sources1**Sponsor****Name of organization / entity**

The Superior University

Full name of responsible person

Gulnaz Yamin

Street address

17 km Raiwind road Lahore

City

Lahore

Postal code

54000

Phone

+92 333 6979114

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

City

Lahore

Province

Punjab

Postal code

54000

Phone

+92 324 4694034

Email

zaheergulnaz4@gmail.com

Web page address

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

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

City

Lahore

Province

Punjab

Postal code

54000

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zaheergulnaz4@gmail.com

Web page address

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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

Street address

17 km 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