Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 epitol 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 (assesor 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 asssor blind technique through which the person who is taking the assesment after the treatment protocol is unawear

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 withChronic 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 $\mu1-\mu2$ and $\sigma1^2 +\sigma2^2$ $n= (Z\ 1-\beta +Z\ \alpha/2) + (\sigma1^2 + \sigma2^2)(\mu1-\mu2)2$Estimated Sample size was60

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 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
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Lahore
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54000
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+92 333 6979114
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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
Street address
17 km Raiwind road Lahore
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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
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Web page address
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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
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