

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparative effects of high and low intensity resistance training on balance and fatigue perception in patients with Parkinson's Disease

Protocol summary

Study aim

To determine the comparative effects of high and low intensity resistance training on balance and fatigue perception in patients with Parkinson's disease.

Design

Parallel group, single-blind, randomized controlled trial on 44 individuals

Settings and conduct

A study was conducted in Physiotherapy Department at District Headquarter Hospital (DHQ) Sheikhpura. A single blinded study and participants were blinded through chit method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: both male and female; 50-65 years old people; Parkinson's disease. Exclusion criteria: cognitive impairments; diagnosed by any other neurological conditions.

Intervention groups

Patients allocated to Group A performed a low-intensity exercise program that included breathing, stretching, and relaxation in a sitting position twice a week for 12 consecutive weeks. In contrast, Participants located in Group B went through high-intensity exercises with Thera-bands twice a week for 12 consecutive weeks with individualized progression. Each session ended up in 60 min. The standard training program included a 5-10 min warm-up session, core activities, and a 5-min cool-down. Outcomes were measured by two scales, Mini-Bestest and Revised Piper Fatigue Scale.

Main outcome variables

Dynamic balance (sensory orientation; dynamic gait; postural instability; anticipatory transitions); Fatigue perception (behavioral/severity; affective meaning; sensory; cognitive/mood).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211107052992N1**

Registration date: **2022-09-18, 1401/06/27**

Registration timing: **retrospective**

Last update: **2022-09-18, 1401/06/27**

Update count: **0**

Registration date

2022-09-18, 1401/06/27

Registrant information

Name

Rida Naqvi

Name of organization / entity

University of Lahore, Lahore (Pakistan)

Country

Pakistan

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-04, 1399/09/14

Expected recruitment end date

2020-12-30, 1399/10/10

Actual recruitment start date

2020-12-04, 1399/09/14

Actual recruitment end date

2020-12-30, 1399/10/10

Trial completion date

2021-03-30, 1400/01/10

Scientific title

Comparative effects of high and low intensity resistance training on balance and fatigue perception in patients with Parkinson's Disease

Public title

Comparative effects of high and low intensity resistance training on balance and fatigue perception in patients with Parkinson's Disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

use stable medicine able to walk 10 m without any kind of assistant either by a person or a walking frame.

Exclusion criteria:

cognitive impairment (Mini-Mental State Examination score lower than 24) comprehension deficits that prevented them from following verbal commands have visual or acoustic limitations diagnosed by any neurological condition other than PD, or other clinical comorbidities that affect the gait

Age

From **50 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **44**

More than 1 sample in each individual

Number of samples in each individual: **3**

Samples were taken 3 times from both group. First time as a baseline. 2nd time after 6 weeks of treatment and third time again after 6 weeks of treatment

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method used. Both group A and B randomized. Participants with Parkinson's Disease in both A and B group randomly selected after matching inclusion criteria through chit method. Random sequence was built by appointing Even numbers to the group A and odd numbers to group B.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants of both groups were blinded in this study through chit method. We had 2 chits on one Group A were written and on other Group B and once they matched the inclusion criteria we gave them both sealed chit and said to choose one. We share general information about the intervention and study protocol with participants of both groups. Participants were informed that they would be randomly allocated into one of the groups and would receive different exercises and Physiotherapy interventions as treatment. Only information about high and low-intensity exercises. After group allocation, they were informed about the detailed intervention plan of their group. Timing of sessions of both groups participants were different to avoid the unintended meetup of the participants.

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of University of Lahore

Street address

University of Lahore, 1 km, Defence Road, Off Bhotatian Chowk, Lahore

City

Lahore

Postal code

55150

Approval date

2020-12-03, 1399/09/13

Ethics committee reference number

IRB-UOL-FAHS/798/2020

Health conditions studied**1****Description of health condition studied**

Parkinson's Disease

ICD-10 code

G20

ICD-10 code description

Parkinson's Disease

Primary outcomes**1****Description**

Balance and Fatigue

Timepoint

baseline, 6 weeks after intervention and 12 weeks after intervention

Method of measurement

Mini-BESTest and Piper Fatigue Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Group A (Intervention group): 22 patients allocated to

the Group A performed low-intensity exercise program which include breathing, stretching and relaxation activities in a sitting position twice a week for 12 consecutive weeks. Each session ended-up in 60 min. The standard training program included 5-10 min warm-up session, core activities and 5-min cool-down.

Category

Rehabilitation

2**Description**

Group B (Intervention group): 22 participants allocated in Group B randomly. Participants allocated to the Group B gone through high intensity resistance training program with thera-bands twice a week for 12 consecutive weeks with individualized progression. Each session ended-up in 60 min. The standard training program included 5-10 min warm-up session, core activities and 5-min cool-down.

Category

Rehabilitation

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

District Headquarter Hospital

Full name of responsible person

Dr. Imran Manzoor Bhatti

Street address

PX6H+PGF, Sheikhpura, Punjab

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

The University of Lahore

Full name of responsible person

Dr. Ashfaq Ahmed

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1-Km Defence Road., near Bhuptian Chowk., Lahore, Punjab

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

The University of Lahore

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Foreign

Category of foreign source of funding

Sponsor: country of origin

Country of origin

PK

Type of organization providing the funding

Academic

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

University of Lahore

Full name of responsible person

Rida Naqvi

Position

Postgraduate Resident

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Full name of responsible person

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

"There is no further information"

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available