

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Effects of 10-week exercise therapy in transverse plane at home on postural stability and initiation of gait in patients with Parkinson's disease: a clinical trial

Protocol summary

Study aim

Evaluation of the effect of 10 weeks of cross-plate home therapy on postural stability and gait of Parkinson's patients

Design

A clinical trial with a control group, with parallel, single-blind, randomized groups on 32 patients

Settings and conduct

The tests are performed before and after the training intervention at Tarbiat Modares University, and the interventions will be performed at the patient care center, which will be controlled by a physiotherapist, often virtually. This is a single-blinded study for the data collectors and outcome assessors.

Participants/Inclusion and exclusion criteria

Idiopathic Parkinson's Patients' H & Y criteria should be between 2-3 Have the ability to walk without assistance Take a fixed dose of medicine Be able to perform simple verbal commands The age of the participants is 40 to 75 Have no specific disorder No diabetes No body mass index of 35 or more Have not had surgery or a regular exercise program in the last 6 months

Intervention groups

Intervention group: transverse plane exercise therapy group plus common exercise therapy for Parkinson's patients Control group: Common exercise therapy group

Main outcome variables

Linear and nonlinear stability metrics based on the excursion of the center of foot pressure (CoP)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210516051322N1**
Registration date: **2021-07-25, 1400/05/03**

Registration timing: **prospective**

Last update: **2021-07-25, 1400/05/03**

Update count: **0**

Registration date

2021-07-25, 1400/05/03

Registrant information

Name

Amir Dodangeh

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-06, 1400/05/15

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of 10-week exercise therapy in transverse plane at home on postural stability and initiation of gait in patients with Parkinson's disease: a clinical trial

Public title

Effects of rotational exercises on the stability of patients with Parkinson's disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Male or female patients with Parkinson's disease diagnosed by a specialist h&y criterion score between 2 and 3 able to walk without assistance Be treated with a fixed dose of dopaminergic drugs during the evaluation and exercise therapy and re-evaluation process able to perform simple verbal commands The age of the participants is 40 to 75

Exclusion criteria:

Existence of a specific musculoskeletal, cardiorespiratory, balance, visual, or cognitive disorder that exercises affect the patient's gait Having diabetes any neurological problem other than Parkinson's DBS surgery in the last 6 months Participating in regular exercise therapy programs for the past 6 months Use of walking aids body mass index of 35 or more

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Having entered the patients in accordance with the inclusion criteria, concealed envelopes containing an equal sample size number of exercise or control statements will be provided to an uninformed person, such as a laboratory expert. He chooses one of the envelopes and thus the patient is placed in one of the two groups of control or exercise (intervention) in a simple and individual way. The result will be hidden only from the participating patient and the researchers are aware.

Blinding (investigator's opinion)

Single blinded

Blinding description

Those responsible for data collection and those assessing the outcome are kept blind to the intervention groups. This is done by assigning neutral codes to the participants (without giving information about patients' intervention grouping like S12).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tarbiat Modares University Ethics Committee

Street address

Jalal AleAhmad., Nasr

City

Tehran

Province

Tehran

Postal code

14115-111

Approval date

2021-06-28, 1400/04/07

Ethics committee reference number

IR.MODARES.REC.1400.098

Health conditions studied

1

Description of health condition studied

Parkinson Disease

ICD-10 code

G20

ICD-10 code description

Parkinson's disease

Primary outcomes

1

Description

Linear and nonlinear metrics of stability based on the excursion of the center of foot pressure (CoP)

Timepoint

Before the intervention and immediately after the intervention(10 weeks after start)

Method of measurement

Force Plate system

2

Description

Parkinson's disease quality of life questionnaire PDQ39

Timepoint

Before the intervention and immediately after the intervention(10 weeks after start)

Method of measurement

questionnaire score using 5-point Likert scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Horizontal plane exercise with common exercises. 5 exercises that include body rotation exercises are added to the usual exercises. Each movement is performed at the beginning of the training sessions in two sets of ten. Between each set, the patient rests for 1 minute and once every two weeks, according to the physiotherapist, the number of exercises is increased by 20%. Exercises are done for 10 weeks and 3 days every week.

Category

Rehabilitation

2

Description

Control group: Common exercise therapy. Each movement is performed at the beginning of the training sessions in two sets of ten. Between each set, the patient rests for 1 minute and once every two weeks, according to the physiotherapist, the number of exercises is increased by 20%. Exercises are done for 10 weeks and 3 days every week.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tarbiat modares university

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Tarbiat Modares University

Full name of responsible person

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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

Research Deputy of Tarbiat Modares University

Proportion provided by this source

100

Public or private sector

Public

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

Tarbiat Modares University

Full name of responsible person

Amir Dodangeh

Position

Master of Physiotherapy Student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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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 processed and analyzed data will be released. These data include the questionnaire scores and linear and nonlinear outcomes of the stability, before and after the interventions.

When the data will become available and for how long

from 6 months after the official publication of results

To whom data/document is available

All academic and clinical researchers

Under which criteria data/document could be used

Only for therapeutical applications, use in neuro-musculoskeletal simulations, and designing rehabilitation assistive devices

From where data/document is obtainable

By contacting the corresponding author of the published papers by email, phone or postal address

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

Process: 1. Determining the data of interest by the applicant 2. contacting the corresponding author to submit the queries by the applicant 3. Reviewing the queries by the research team 4. Responding to the queries till 10 working days by the research team

Comments