Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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
Mohammed Najafi Ashtiani

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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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Person responsible for scientific inquiries

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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