

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of the effect of receiving feedback from healthy subjects and patients with Parkinsons disease while performing group balance task-oriented exercises on postural control in patient with Parkinsons disease

Protocol summary

Summary

The aim of this study is to compare the effect of receiving feedback from healthy subjects and patients with Parkinson's disease in group balance exercises on balance of patient with Parkinson's disease. In this clinical trial study, 40 patients with idiopathic Parkinson's disease are randomly assigned to two groups: a group receiving feedback from healthy subjects and a group receiving feedback from patients with Parkinson's disease. The main inclusion criteria include having Parkinson's disease according to the neurologist diagnosis, having the disease's progression level of 1 to 3 as measured by Hoehn and Yahr Scale, an acceptable level of cognitive function, i.e. score of more than 21 on the Mini Mental Status Examination (MMSE). Subjects are excluded if they do not cooperate during the test and exercises and not return for testing after the intervention. Twenty-four sessions of group balance exercises are performed with receiving feedback from healthy subjects and patients with Parkinson's disease (8 weeks, 3 sessions per week, 60 minutes per session). Functional balance and postural control are evaluated with clinical and laboratory tests before and after receiving exercises in both group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092416830N5**
Registration date: **2015-11-24, 1394/09/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-24, 1394/09/03

Registrant information

Name

Ghorban Taghizadeh

Name of organization / entity

School of Rehabilitation Sciences, Iran University of Medical

Country

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Recruitment status

Recruitment complete

Funding source

Dr. Seyed Ali Javad Mousavi, Vice Chancellor for research of Iran University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of receiving feedback from healthy subjects and patients with Parkinsons disease while performing group balance task-oriented exercises on postural control in patient with Parkinsons disease

Public title

The comparison of the effect of receiving feedback from healthy subjects and patients with Parkinsons disease in group balance exercises on balance of patient with Parkinsons disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria for patients with Parkinson's disease: Having Parkinson's disease according to neurologist diagnosis; Having the disease's progression level of 1 to 3 as measured by Hoehn and Yahr Scale; Having an acceptable level of cognitive function, i.e. score of more than 21 on the Mini Mental Status Examination; Having the ability to walk independently and without assistive device at least 10 meters in length; Having at least a fifth grade education; Not having any other neurological diseases such as stroke according to the patient, or the patient's family or physician report; Not having any orthopedic problem according to the patient, or the patient's family or physician report; Not having diabetes or addiction according to the patient, or the patient's family or physician report; Not having pathologic dementia according to neurologist diagnosis; Not having Juvenile Parkinsonism. Inclusion Criteria for healthy subjects: No known pathological problems, according to the person and family report. Exclusion Criteria for patients with Parkinson's disease: Lack of patient cooperation during the test or exercises; Not return for doing tests after the intervention; Entering to the nonpharmacologic on-off phase of the disease during the study according to neurologist diagnosis; Change in the pharmacologic regimen of the patient during the study. Exclusion Criteria for healthy subjects: Lack of cooperation during the test or exercises.

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Hemmat Highway, Tehran

City

Tehran

Postal code

Approval date

2015-09-22, 1394/06/31

Ethics committee reference number

IR.IUMS.rec.1394.26527

Health conditions studied

1

Description of health condition studied

Parkinson's disease

ICD-10 code

G20

ICD-10 code description

Extrapyramidal and movement disorders

Primary outcomes

1

Description

Postural control

Timepoint

before and after intervention

Method of measurement

Forceplate

Secondary outcomes

1

Description

Functional balance and mobility

Timepoint

before and after intervention

Method of measurement

Berg Balance Scale, Functional Reach test, Timed Up and Go, 6 Minutes Walking test

Intervention groups

1

Description

Group receiving group balance exercises with feedback from healthy subjects: Twenty- four sessions of group balance exercises with receiving feedback from healthy subjects (8 weeks, 3 sessions per week, 60 minutes per session)

Category

Rehabilitation

2**Description**

Group receiving group balance exercises with feedback from patients with Parkinson's disease: Twenty-four sessions of group balance exercise with receiving feedback from patients with Parkinson's disease (8 weeks, 3 sessions per week, 60 minutes per session)

Category

Rehabilitation

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

Occupational therapy clinic, Faculty of Rehabilitation, Iran University of Medical Sciences

Full name of responsible person

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Occupational Therapy Department, Faculty of Rehabilitation Sciences, Iran University of Medical Sciences, Shahnazari Street, Mirdamad Boulevard, Tehran, Iran

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

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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

Dr. Seyed Ali Javad Mousavi, Vice Chancellor for research of Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty