

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of cognitive and motor dual task training on improvement of balance, some kinematic parameters of gait cycle and fear of falling in people with idiopathic Parkinson's disease

Protocol summary

Study aim

The effect of cognitive and motor dual task training on improvement of balance, some kinematic parameters of gait cycle and fear of falling in people with idiopathic Parkinson's disease

Design

Clinical trial with two intervention groups and one control group, no blinded, no randomized

Settings and conduct

This is a quasi-experimental study. Subjects will be assessed before training, after ten weeks training, and one month after the last session of training in Poursina Hospital in Rasht.

Participants/Inclusion and exclusion criteria

Inclusion criteria: To have II-III score in Hoehn- Yahr scale; to be able to walk independently to 100 meters; to be able to do simple orders Exclusion criteria: Subjects with cardiovascular and pulmonary disorders; subjects with significant cognitive disorders

Intervention groups

Intervention groups: Cognitive dual task training; motor dual task training Control group: exercise group without dual task training

Main outcome variables

balance; some kinematic parameters of gait cycle; fear of falling; quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180106038239N1**

Registration date: **2018-03-03, 1396/12/12**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-03, 1396/12/12**

Update count: **0**

Registration date

2018-03-03, 1396/12/12

Registrant information

Name

Tahereh Pourkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 4222 3783

Email address

zpourkhani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cognitive and motor dual task training on improvement of balance, some kinematic parameters of gait cycle and fear of falling in people with idiopathic Parkinson's disease

Public title

The effect of exercise in people with idiopathic Parkinson's disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
 PD patients diagnosed with Hoehn and Yahr score of 2 or 3 Prescribed one or more anti-parkinsonism medications by a consultant neurologist or consultant physician with specialist knowledge of neurological disorders Stable medication use; that is, not altered within the previous month and not expected to change during next 3 months Willing to be assigned to any of the three interventions Able to walk 100 m independently with or without gait aids; Able to do simple orders and getting a score more than 24 on the Mini-Mental Status Examination (MMSE) Age between 50-75 Getting a score less than 14 in Beck Depression Inventory

Exclusion criteria:
 Any clinical condition that make it impossible to use physical effort Patients with cardiovascular and pulmonary diseases Significant physical limitations Sensory system pathology affecting walking (e.g. blindness, deafness). To have a surgery for PD such as deep brain stimulation Suspected Parkinsonism due to causes other than idiopathic PD. Current participation in any other behavioral or exercise programs. Participation of a structured exercise program in the preceding 2 months. Unavailability during the period of the study. Patients with dementia or significant cognitive impairment

Age
 From **50 years** old to **75 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **36**

Randomization (investigator's opinion)
 Not randomized

Randomization description

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Syadati street, Namjou Avenue

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2017-12-16, 1396/09/25

Ethics committee reference number

IR.GUMS.REC.1396.381

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

The ability of body for keeping the equilibrium.

Timepoint

Before training, after ten weeks of training, after one month of the last session of training

Method of measurement

Up and go test

2

Description

kinematic parameters of gait cycle

Timepoint

Before training, after ten weeks of training, after one month of the last session of training

Method of measurement

by motion analyzer system

3

Description

fear of falling

Timepoint

Before training, after ten weeks of training, after one month of the last session of training

Method of measurement

Falls Efficacy Scale-International

4

Description

quality of life

Timepoint

Before training, after ten weeks of training, after one

month of the last session of training
Method of measurement
quality of life assessment questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: cognitive dual task training: In addition to exercise protocol during 10 weeks, three times a week and 45 minutes per session, subjects will do a cognitive task like reverse counting by three, to answer to the examiner's cognitive questions, to learn a list of words and repeat them after sets of exercises, simultaneously.

Category

Rehabilitation

2

Description

The second intervention group: motor dual task training: In addition to exercise protocol during 10 weeks, three times a week and 45 minutes per session, subjects will do a motor task like carrying a dish with a water glass on it, buttoning up the blouse or shirt, to take objects like wallet or cell phone from the pocket

Category

Rehabilitation

3

Description

Control group: to do exercise protocol during 10 weeks, three times a week and 45 minutes per session

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

The Poursina Hospital

Full name of responsible person

Dr Seyed Mehdi Zyabari

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Parastar

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41937-13194

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poursina_pr@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

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Syadati Ave. Namjoo Street, Rasht

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nemati@gums.ac.ir

Web page address

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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

Rasht University of Medical Sciences

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Tahereh Pourkhani

Position

Physical Therapist

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available