

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 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

##### Street address

Parastar

##### City

Rasht

##### Province

Guilan

##### Postal code

41937-13194

##### Phone

+98 13 3332 2444

#### Fax

+98 13 3333 9842

#### Email

poursina\_pr@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rasht University of Medical Sciences

##### Full name of responsible person

Dr Shadman Nemati

##### Street address

Syadati Ave. Namjoo Street, Rasht

##### City

Rasht

##### Province

Guilan

##### Postal code

4415735551

##### Phone

+98 13 3333 5820

##### Fax

+98 13 3333 6395

##### Email

nemati@gums.ac.ir

##### Web page address

<http://www.gums.ac.ir>

#### 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

**Street address**

Khalije Fars Avenue

**City**

Rasht

**Province**

Guilan

**Postal code**

4199613776

**Phone**

+98 13336904858

**Email**

zpourkhani@gmail.com

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

Rasht University of Medical Sciences

**Full name of responsible person**

Tahereh Pourkhani

**Position**

PhD Student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

No. 44, 3rd Nima Street

**City**

Lahidjan

**Province**

Guilan

**Postal code**

4415735551

**Phone**

+98 13 4222 3783

**Fax****Email**

zpourkhani@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Rasht University of Medical Sciences

**Full name of responsible person**

Tahereh Pourkhani

**Position**

Ph D Student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

No. 44, 3rd Nima Street

**City**

Lahidjan

**Province**

Guilan

**Postal code**

4415735551

**Phone**

+98 13 4222 3783

**Email**

zpourkhani@gmail.com

**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