

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

The effect of vestibular exercises on fatigue in patients with parkinson's disease

Protocol summary

Summary

Objectives: The purpose of this study is to evaluate the effect of vestibular exercises on fatigue in patients with Parkinson's disease. Design: Participants are selected from men and women with Parkinson, aged 50 and older. 28 participants are randomly assigned into control and intervention groups by coded envelopes. Setting and conduct: Evaluations are done two times before and after the intervention by a trained Occupational Therapist who is blind to type of groups. Participants: Subjects must be in level 1 to 4 of Parkinson. Intervention: After the baseline assessments, treatment sessions are given, 3 sessions per week, each session about 55-60 minutes for 24 sessions. Vestibular exercises are classified into five general categories, including the body standing without moving on the ground, the body in the form of a stench on the floor, the body standing on the trampoline, walking, and, finally, exercises related to the movements of the eye. Main outcome measures: Functional Independence Measure and Parkinson Fatigue Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201709123551N6**

Registration date: **2017-09-28, 1396/07/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-28, 1396/07/06

Registrant information

Name

Parvin Raji

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7753 8798

Email address

praji@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for education and research, Tehran University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vestibular exercises on fatigue in patients with parkinson's disease

Public title

The effect of vestibular exercises on fatigue in patients with parkinson's disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The diagnosis of Parkinson's disease according to the neurologist; absence of severe visual and auditory disorders; lack of diabetes; osteoarthritis and osteoporosis, especially in the lower limbs; any other neurological disease including stroke; having a Parkinson level of 1 to 4 according to Hoehn and Yahr; all tests and evaluations are done in the phase of the drug (when the

medication has most of its effects and symptoms associated with non-drug use have completely subsided), if consumed, it should be discontinued 24 hours before the videonistagmography test; The ability to walk with or without auxiliary equipment at least 100 meters in length; Having a cognitive level above 23 in the MMSE exam; Having fatigue with a mean score of 3.3 according to the Parkinson Fatigue Scale and lack of severe depression (score less than 29) based on the Beck depression inventory; Diagnosis of Central Vestibular Disorder by Audiologist by (VNG) Test Videonystagmography; Not having severe sleep disorder using the Pittsburgh Sleep Quality Index (PSQI-P) score less than 5, and lack of stress and anxiety (score less than 78) by The Depression Anxiety Stress Scales (DASS) Exclusion criteria: Failure to co-operate with the patient during tests and exercises; Failure to return a patient to perform second-stage tests after interventions; Patients undergoing a change in their diet

Age

From **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

randomization by coded envelop

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Poursina St, Ghods St, Keshavarz Blvd

City

Tehran

Postal code**Approval date**

2017-08-15, 1396/05/24

Ethics committee reference number

IR.TUMS.FNM.REC.1396.3210

Health conditions studied**1****Description of health condition studied**

Parkinson disease

ICD-10 code

G20

ICD-10 code description

Parkinson disease

Primary outcomes**1****Description**

Parkinson Fatigue

Timepoint

before and immediately after the end of the intervention

Method of measurement

Questionnaire (Parkinson Fatigue Scale)

Secondary outcomes**1****Description**

Functional Independence

Timepoint

before and immediately after the end of the intervention

Method of measurement

Questionnaire (Functional Independence Measure)

Intervention groups**1****Description**

Control group: muscle stretching+ fatigue management

Category

Rehabilitation

2**Description**

Intervention group: muscle stretching+ fatigue management + vestibular exercises

Category

Rehabilitation

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

educational and interventional centers of Tehran University of Medical Sciences

Full name of responsible person

Amir Abbas Abbasi

Street address**City**

تهران

praji@tums.ac.ir

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

Tehran University of Medical Sciences

Full name of responsible person

Mohammadreza Hadian

Position

Professor

Other areas of specialty/work**Street address**

Rehabilitation faculty of Tehran University of Medical Sciences, Picheshemiran, Enghelab Ave

City

Tehran

Postal code**Phone**

+98 21 7753 3939

Fax**Email**

hadian_ras@yahoo.com; hadianrs@sina.tums.ac.ir

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for education and research, Tehran University of Medical Sciences

Full name of responsible person

Dr Mohammad Jalili, Dr Masud Yunesian

Street address

Vice chancellor for education and research, Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd, Tehran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for education and research, Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Parvin Raji

Position

Lecturer

Other areas of specialty/work**Street address**

Rehabilitation faculty of Tehran University of Medical Sciences, Picheshemiran, Enghelab Ave, Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 7753 3939

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

Tehran University of Medical Sciences

Full name of responsible person

Parvin Raji

Position**Other areas of specialty/work****Street address**

Rehabilitation faculty of Tehran University of Medical Sciences, Picheshemiran, Enghelab Ave Tehran

City**Postal code****Phone**

00

Fax**Email****Web page address****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