

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of vibration orthosis in the cervical paraspinal muscles on dynamic balance and walking speed in patients with Parkinson's disease.

#### Protocol summary

##### Study aim

The effect of sensory mechanical stimulation in the form of neck vibration on walking speed

##### Design

This is a pre- and post -intervention study in which the samples will be randomly selected.

##### Settings and conduct

Patients are referred to the study after completing clinical assessments and completing the assessment on a Hoehn and Yahr scale. Biodex balance machine (Model 30 D\_E6N\_Sw45) in dynamic mode is used to evaluate patient balance. The overall stability index is a specific equilibrium measurement factor and is extracted by the output of the biodex balancing device, and in various situations without vibration orthosis, the vibration orthosis is closed with the motor off. And the light engine is compared. Evaluation of patients' walking speed is performed in three stages by Timed UP and GO test: without closing the vibrating neck orthosis, with vibrating orthosis while the motor is off, with vibrating orthosis while the motor is on . After the patient's initial examination for one month, he/she visits the Physical Medicine and Rehabilitation Department of Firoozgar Hospital for one month a week and receives electrical stimulation through vibration orthosis. Do the same with the methods mentioned above.

##### Participants/Inclusion and exclusion criteria

inclusion criteria : People 50-80 years with Parkinson's disease ,Being in one of stages 2 to 4 of the disease severity scale on the Hoehn and Yahr scale ,Having a stable medication regimen for at least the past 3 months  
exclusion criteria : Having a history of falling in the past 6 months , other neurological or mental illnesses ,cardiovascular disease

##### Intervention groups

The vibration orthosis device is placed on the paraspinal cervical muscles of patients with Parkinson's disease and the patient walks with the device for 15 minutes.

##### Main outcome variables

overall stability index measured with biodex balance machine, Timed Up and Go test.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190306042945N3**

Registration date: **2019-11-03, 1398/08/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-11-03, 1398/08/12**

Update count: **0**

##### Registration date

2019-11-03, 1398/08/12

##### Registrant information

##### Name

Bijan Forogh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8214 1612

##### Email address

forogh.b@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-12, 1398/07/20

##### Expected recruitment end date

2019-11-11, 1398/08/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of vibration orthosis in the cervical paraspinal muscles on dynamic balance and walking speed in patients with Parkinson's disease.

**Public title**

The effect of vibration orthosis in the cervical paraspinal muscles on dynamic balance and walking speed in patients with Parkinson's disease.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

People 50-80 years with Parkinson's disease Being in one of stages 2 to 4 of the disease severity scale on the Hoehn and Yahr scale Having a stable and specific medication regimen for at least the past 3 months

**Exclusion criteria:**

Having a history of falling in the past 6 months Having a history of other neurological or mental illnesses Having a history of cardiovascular disease Having musculoskeletal disease

**Age**

From **50 years** old to **80 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **15**

**Randomization (investigator's opinion)**

N/A

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

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

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

committee of Iran University of Medical Sciences Street address

**Street address**

Iran University of Medical Sciences ,Hemmat Highway ,Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2019-01-16, 1397/10/26

**Ethics committee reference number**

IR.IUMS.FMD.REC.1397.248

**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**

Dynamic Equilibrium Rate

**Timepoint**

zero ,4 weeks, 8 weeks

**Method of measurement**

Biodex Balancing Machine

**2****Description**

Walking speed

**Timepoint**

zero ,4 weeks ,8 weeks.

**Method of measurement**

Timed Up and Go test

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

side effects

**Timepoint**

4 weeks ,8 weeks.

**Method of measurement**

physical examination

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

Intervention group: Vibration in the paraspinal cervical muscle area by inserting a vibrating orthosis in the Neck, By researcher

**Category**

Treatment - Devices

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

Firoozgar hospital

**Full name of responsible person**

Fahime notghy

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Valadi Ave, Valie asr Blvd, Tehran Town

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**Postal code**

1593747811

**Phone**

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Dr.notghi@gmail.com

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

Iran University of Medical Sciences

**Full name of responsible person**

Abbas Motevallian

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Medical science**City**

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amotevalian@iums.ac.ir

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

Yes

**Title of funding source**

Iran 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**

Academic

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

Iran University of Medical Sciences

**Full name of responsible person**

Fahime Notghi

**Position**

Resident of Physical Medicine and Rehabilitation

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

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

Iran University of Medical Sciences

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Bijan Forogh

**Position**

Professor of Physical Medicine and Rehabilitation

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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## Person responsible for updating data

### Contact

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Iran University of Medical Sciences

**Full name of responsible person**

Fahime Notghi

**Position**

Resident of Physical Medicine and Rehabilitation

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

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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