Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of textured insoles compared with vibrating insoles on spatio-temporal parameters of gait, static and dynamic balance in people with Parkinson's disease

Protocol summary

Study aim
Investigating the effect of textured insoles compared to vibrating insoles on spatio-temporal parameters of gait, static balance, and dynamic balance in people with Parkinson's disease

Design
Clinical trial without control group, with parallel groups, without blinding, randomized, on 16 patients. Blocking method is used for randomization.

Settings and conduct
This study is a prospective clinical trial and its design is a repeated-measures study with within-group and between-group factors. It will be conducted in 2025 at the Musculoskeletal Disorders Research Center, Faculty of Rehabilitation Sciences, Isfahan University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People with mild to moderate Parkinson's disease, Aged between 60 and 70, Idiopathic Parkinson's disease patients without comorbidities, Patients with idiopathic Parkinson's disease whose body mass index (BMI) is between 25 and 35 kg/m2. Exclusion criteria: Neurological disorders, Any deformity in the lower limbs that affects the patient's gait.

Intervention groups
The first group uses a textured insole for a week. The textured insole will consist of four main parts: the base insole, a 15mm internal longitudinal arch, a heel cup, and a textured surface on the insole. This insole is full-length and covers the heel area to the end of the toes. The second group uses a vibrating insole for a week. The vibrating insole will have two main parts: static and a vibration system. The static part is a prefabricated insole, and the vibration system of the vibrating insole includes vibration motors, a control center, and a power source. Both types of insoles are prepared at the Orthotics and Prosthetics Clinic of the Isfahan Faculty of Rehabilitation Sciences.

Main outcome variables
Walking speed, Stride rate, Stride length, Average displacement of center of pressure, Average displacement of body center of mass

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211030052916N2**
Registration date: **2025-05-13, 1404/02/23**
Registration timing: **prospective**

Last update: **2025-05-13, 1404/02/23**
Update count: **0**

Registration date
2025-05-13, 1404/02/23

Registrant information

Name
Amirhossein Zare

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-22, 1404/04/01

Expected recruitment end date
2025-08-22, 1404/05/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of textured insoles compared with vibrating insoles on spatio-temporal parameters of gait, static and dynamic balance in people with Parkinson's disease

Public title
Textured insole and vibrating insole on balance and gait parameters of people with Parkinson's disease
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
People with mild to moderate Parkinson's or grades 2 and 3 on the Hohen-Yarn scale Patients can walk without assistive devices in their daily activities Idiopathic Parkinson's patients without comorbidities Patients with idiopathic Parkinson's disease whose Body Mass Index (BMI) is between 25 and 35 Kg/m2
Exclusion criteria:
Uncorrected visual impairment Postural hypotension Known orthopedic or arthritic disease affecting gait Any deformity of the lower extremities (hip, knee, ankle, and foot) that affects the patient's gait
Age
From **60 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **16**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: Block randomization
Randomization tool: Draw by paper selection
Randomization method: In order to control confounding variables, participants are randomly assigned to two equal test groups (1- vibrating insole 2- textured insole). The random assignment method in both groups is as follows: the size of each block is 4 people, and accordingly, by considering two groups (textured insole = P1, vibrating insole = P2), 6 blocks are obtained. These blocks are written separately on paper and poured into a container, and 8 people are selected for each group by drawing lots, and 16 people in total.
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
Research Ethics Committees of Nursing, Rehabilitation & Management schools
Street address
Research Ethics Committees of Nursing, Rehabilitation & Management Schools, Faculty of Rehabilitation Sciences, Isfahan University of Medical Sciences, Hezarjarib Street, Isfahan
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Approval date
2025-04-29, 1404/02/09
Ethics committee reference number
IR.MUI.NUREMA.REC.1404.016

Health conditions studied

1

Description of health condition studied
Parkinson disease
ICD-10 code
G20
ICD-10 code description
Parkinson's disease

Primary outcomes

1

Description
Walking speed
Timepoint
Time periods for measuring study parameters: at the beginning of the study (before the intervention), immediately after the intervention (baseline), and 7 days after the intervention (baseline)
Method of measurement
Specialized gait analysis laboratory, force plate device and force plate evaluator

2

Description
Stride Length
Timepoint
Time periods for measuring study parameters: at the

beginning of the study (before the intervention), immediately after the intervention (baseline), and 7 days after the intervention (baseline)

Method of measurement

Specialized gait analysis laboratory, force plate device and force plate evaluator

3

Description

Cadence

Timepoint

Time periods for measuring study parameters: at the beginning of the study (before the intervention), immediately after the intervention (baseline), and 7 days after the intervention (baseline)

Method of measurement

Specialized gait analysis laboratory, force plate device and force plate evaluator

4

Description

Average displacement of the center of pressure

Timepoint

Time periods for measuring study parameters: at the beginning of the study (before the intervention), immediately after the intervention (baseline), and 7 days after the intervention (baseline)

Method of measurement

Specialized gait analysis laboratory, force plate device and force plate evaluator

5

Description

Average displacement of the body's center of mass

Timepoint

Time periods for measuring study parameters: at the beginning of the study (before the intervention), immediately after the intervention (baseline), and 7 days after the intervention (baseline)

Method of measurement

Specialized gait analysis laboratory, force plate device and force plate evaluator

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group one: Patients with Parkinson's who use a textured insole. The textured insole will consist of four main parts: the base insole, a 15 mm medial longitudinal arch, a heel cup (made of foam with a hardness of A50), and a textured surface on the insole. This insole is full-length and covers the heel area to the ends of the toes. This insole is prepared for people with Parkinson's based on the patient's foot measurements (toe and heel width, foot length, and medial longitudinal arch length) by a prosthetic orthotist at the Technical Orthopedic Clinic of the Faculty of Rehabilitation Sciences of Isfahan University of Medical Sciences. In fact, the upper surface of the insole has a textured design of 5 mm in height and 2 mm in thickness and is in contact with the patient's sole. The reason for this choice is the report of previous research on the stimulation of mechanoreceptors in the sole of the foot. Each Parkinson's patient selected for the study wore a pair of textured insoles and underwent laboratory tests twice (once immediately after wearing the textured insoles and the second time, one week after using the textured insoles). The method of using the textured insole is that the patient places the insole inside his shoe and immediately performs the research-related tests, and after using the insole inside the shoe for a week, he performs the research tests again. The duration of use of the textured insole is such that the patient uses the textured insole inside the shoe whenever he wants to walk inside or outside the house.

Category

Treatment - Devices

2

Description

Second intervention group: Patients with Parkinson's who use a vibrating insole. In this study, the vibrating insole will have two main parts (static and vibration system). The static part is a prefabricated insole and includes three main parts: the base insole, the internal longitudinal arch with a height of 15 mm, and the heel cup (made of foam with a stiffness of A50). This insole is full-length and covers the heel to the tips of the toes. This insole is prepared for people with Parkinson's based on the patient's foot measurements (toe and heel width, foot length, and internal longitudinal arch length) by a prosthetic orthotist and in the Technical Orthopedic Clinic of the Faculty of Rehabilitation Sciences, Isfahan University of Medical Sciences. The vibration system of the vibrating insole includes vibration motors, a control center, and a power supply. Mechanical vibration motors with a diameter of 8 mm, a thickness of 2.7 mm, and a durable steel material will be embedded in the prefabricated insole and will be used as the vibration actuator of the vibrating insole. The mechanical vibration motors will be placed under the heads of the 1st and 5th metatarsals and the heel area. The vibration motors will be connected to the control center via flexible wires with a diameter of 1 mm made of silver fiber. A dedicated electronic circuit will be designed to adjust the type and level of vibration. The power source will be a lithium battery. The battery and control circuit will be placed in a box that will be fastened with a strap to the top and outside of the person's ankle. Each Parkinson's patient selected for the study will wear a pair of vibrating insoles and perform laboratory tests twice (once immediately after wearing the vibrating insoles and the second time, one week after using the vibrating insoles). The method of using the vibrating insole is that the patient places the insole inside his shoe and immediately performs the research-related tests, and after using the insole inside

the shoe for a week, he performs the research tests again. The duration of use of the vibrating insole is such that whenever the patient wants to walk inside or outside the house, he uses the textured insole inside the shoe.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Musculoskeletal Center, Faculty of Rehabilitation Sciences

Full name of responsible person
Ebrahim Sadeghi Demneh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Esfahan 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
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Full name of responsible person
Amirhossein Zare

Position
PhD Student

Latest degree
Master

Other areas of specialty/work
Technical Ortopedics

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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

Yes - There is 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

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

Access period starts 6 months after results are published.

To whom data/document is available

The data from the present study will be available to researchers working in academic and scientific institutions and people working in industry.

Under which criteria data/document could be used

In addition to the individuals listed above, thesis reviewers and the Musculoskeletal Research Center of the Faculty of Sciences of Tunbakhshi may receive data without personal identification.

From where data/document is obtainable

Applicants can receive the research data by emailing and contacting Dr. Masoud Rafiaei. Email: ma.rafiaei@gmail.com

What processes are involved for a request to access data/document

After the applicant's request, the supervisor consults with the research team and announces the final decision regarding the type of request within one month of receiving the email.

Comments