

Effects of vibrating insoles on improving peripheral sensation in people with diabetic peripheral neuropathy

| | | |
|--|--|--|
| Submission date 14/07/2023 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 16/08/2023 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 06/02/2025 | Condition category Nervous System Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Vibrating insoles have been shown to improve standing balance. People with diabetes are known to experience difficulties balancing, so an insole to improve balance control during walking may help prevent falls. This study investigates a range of types of vibration to establish which type of vibration gives the best improvement in balance. People who have been diagnosed with diabetes and have been identified as having some level of loss of sensation in the feet are eligible to participate in the study.

Who can participate?

Adult patients aged between 18 and 90 years old with a diagnosis of type 2 diabetes mellitus and moderate diabetic peripheral neuropathy plus the presence of at least one pedal pulse

What does the study involve?

Participants will be invited to visit the Gait and Biomechanics Laboratory at Manchester Metropolitan University in Manchester. During the study visit, they will undergo various tests related to movement and diabetes, including sensory assessment, questionnaires and a series of tests, including standing tests, walking and stair climbing.

What are the possible benefits and risks of participating?

There are no direct benefits from taking part in the current study. However, this study has been developed to inform a clinical trial where we will invite people to test a vibrating insole device in their daily life, to establish how well it benefits people by improving balance during daily activities.

Where is the study run from?

Manchester Metropolitan University (UK)

When is the study starting and how long is it expected to run for?

November 2018 to April 2022

Who is funding the study?
Horizon EUROPE SME Instrument grant. Project number: 879948.

Who is the main contact?
Prof Neil Reeves, n.d.reeves1@lancaster.ac.uk

Contact information

Type(s)

Scientific, Principal Investigator

Contact name

Prof Neil Reeves

ORCID ID

<http://orcid.org/0000-0001-9213-4580>

Contact details

Medical School, Faculty of Health and Medicine, Lancaster University, Health Innovation One
Building
Lancaster
United Kingdom
LA1 4YW

-

n.d.reeves1@lancaster.ac.uk

Type(s)

Public

Contact name

Dr Giorgio Orlando

ORCID ID

<http://orcid.org/0000-0001-6721-8248>

Contact details

Senior Research Associate
Manchester Metropolitan University
John Dalton Building, Chester Street
Manchester
United Kingdom
M1 5GD
+44 (0)161 247 1358
g.orlando@mmu.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

273101

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 273101

Study information

Scientific Title

An investigation of a smart insole, for the purpose of improving sensory response in people with diabetic peripheral neuropathy - SMARTSOLE

Acronym

SMARTSOLE

Study objectives

The optimal vibrational type for improving sensory perception and balance control in people with diabetic peripheral neuropathy (DPN) remains unknown. The current study will assess different types of vibrational stimuli provided by a vibrating insole device, to determine the conditions providing optimal improvement in sensory perception and balance control during dynamic and static tasks in diabetic patients with DPN.

Ethics approval required

Ethics approval required

Ethics approval(s)

1. Approved 05/11/2020, North West - Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; None available; gmeast.rec@hra.nhs.uk), ref: 20/NW/0372

2. Approved 16/10/2020, MHRA (10 South Colonnade Canary Wharf, London, E14 4PU, United Kingdom; +44 (0)20 3080 6521; agnes.botchey@mhra.gov.uk), ref: CI/2020/0026

Study design

Single-blind randomized cross-sectional crossover-design intervention trial

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

University/medical school/dental school

Study type(s)

Prevention, Quality of life, Efficacy

Participant information sheet

See trial outputs table

Health condition(s) or problem(s) studied

Diabetic peripheral neuropathy due to type 2 diabetes

Interventions

The optimal vibration stimuli for improving balance in people with DPN remains unknown. Our study will thus explore the impact of different vibratory conditions on gait and balance in people with DPN.

Every participant will attend a one-day session at the biomechanics lab of the Manchester Metropolitan University where he will wear a vibrating insoles system. Participants will be randomly exposed to seven different vibratory stimuli and one control condition (without vibration) for a total of eight conditions. The vibratory conditions will vary based on different parameters, including frequency, type of activation, the addition or otherwise of white noise, and the location of vibration. The order of the eight conditions will be determined by a random number generator.

The insole device will be inserted in standardised footwear (furnished to the participants) and will deliver vibration for the duration of the functional tasks, including standing tests, walking and stair negotiation. Participants will have a rest time (10 minutes) and a period of acclimatisation (10 minutes) to each new vibration setting. Every session will require approximately 5 hours. Gait kinematics and balance data will be collected using a 3D Motion capture system and force platforms after each condition. A highly skilled researcher on diabetic foot and biomechanics will manage and monitor the vibratory intervention and collect biomechanical data. The researcher will be trained in the use of the vibrating insole system and 3D Motion capture system.

Intervention Type

Device

Pharmaceutical study type(s)

Not Applicable

Phase

Phase II

Drug/device/biological/vaccine name(s)

Path feel vibrating insole system, developed by Walk With Path (Denmark).

Primary outcome measure

Postural sway during standing, walking and stair negotiation are measured using a 3D motion capture system and force platforms before and after each vibration condition

Secondary outcome measures

1. Gait kinematics and kinetics are measured using a 3D motion capture system and force platforms before and after each vibration condition
2. Muscle activation using surface electromyography (sEMG) before and after each vibration condition

Overall study start date

10/11/2018

Completion date

30/04/2022

Eligibility

Key inclusion criteria

1. Diagnosis of type 2 diabetes mellitus
2. Aged >18 years
3. Presence of at least one pedal pulse
4. Presence of moderate diabetic peripheral neuropathy defined by a vibration perception threshold > 15V
5. Ability to walk unaided for 30 steps
6. Able to understand all of the study requirements
7. Fit shoe size UK 8-12

Participant type(s)

Patient

Age group

Mixed

Lower age limit

18 Years

Upper age limit

90 Years

Sex

Male

Target number of participants

23

Total final enrolment

22

Key exclusion criteria

1. Active foot ulcer
2. NHS prescription footwear
3. Lower limb amputation (anything more than amputation of two lesser toes)
4. Severe deformity due to Charcot Neuroarthropathy
5. Major foot deformities, including diabetes and non-diabetes-related deformities
6. Dementia or other cognitive impairment
7. Significant cardiopulmonary or other systemic disease limiting the patient's ability to walk 30 steps
8. Person with bodyweight greater than 100kg (due to insole device limitations)
9. Use of a pacemaker
10. Inability to understand verbal and written information in English

Date of first enrolment

25/10/2020

Date of final enrolment

01/12/2021

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Manchester Royal Royal Infirmary**

Cobbett House

Oxford Road

Manchester

United Kingdom

M13 9WL

Study participating centre**Tameside and Glossop Integrated Care NHS Foundation Trust**

Ashton under Lyne

Manchester

United Kingdom

OL6 9RW

Sponsor information

Organisation

Manchester Metropolitan University

Sponsor details

Faculty of Science and Engineering

John Dalton Building

Oxford Road

Manchester

England

United Kingdom

M1 5GD

+44 (0)161 247 2000

n.reeves@mmu.ac.uk

Sponsor type

University/education

Website

<http://www2.mmu.ac.uk/>

ROR

<https://ror.org/02hstj355>

Funder(s)

Funder type

Government

Funder Name

HORIZON EUROPE Framework Programme

Alternative Name(s)

Horizon Europe, Horizon Europe Programme, Framework Programme, Horizon Europe, EU Framework Programme, Horizon

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Results and Publications

Publication and dissemination plan

Planned publication in a high impact peer reviewed journal

Intention to publish date

31/12/2023

Individual participant data (IPD) sharing plan

The dataset generated during and/or analysed during the current study is not expected to be made available due to commercial sensitivity.

IPD sharing plan summary

Not expected to be made available

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------|---------|--------------|------------|----------------|-----------------|
|-------------|---------|--------------|------------|----------------|-----------------|

| | | | | | |
|---|--------------|------------|------------|-----|-----|
| Participant information sheet | version 01.3 | 15/10/2020 | 15/08/2023 | No | Yes |
| Results article | | 01/06/2024 | 06/06/2024 | Yes | No |