ISRCTN15526470 https://doi.org/10.1186/ISRCTN15526470

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

Submission date
14/07/2023

Recruitment status
No longer recruiting

Registration date
16/08/2023

Overall study status
Completed

Last Edited
06/02/2025

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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Public

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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
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OL6 9RW

Sponsor information

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Sponsor type
University/education

Website
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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