

# A multicentre, randomised controlled feasibility study to compare the effectiveness of a novel instant optimised insole with a standard insole for people with diabetic neuropathy

<b>Submission date</b> 25/09/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 09/10/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/02/2023	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

One of the common problems associated with diabetes is the development of foot ulcers. These are frequently associated with high pressure areas and loss of feeling in the feet. Insoles and specialist shoes are often provided to move the pressure from the high impact areas to other parts of the foot to try and either heal the ulcer or reduce the risk of ulcers occurring. Unfortunately there are frequent delays in providing the insoles and shoes and no way of testing how efficient they are in moving the pressure around the foot. Therefore the National Institute of Health Research have funded a study to compare 2 groups of people with diabetes and sensory neuropathy that have been categorised as high risk of developing a foot ulcer. One group are given special insoles made using new technology (a sensor that fits inside the patient's shoe measuring the walking pressures under the foot) and the other will be given plain cushioned insoles. The aim of this study is to determine whether there is any difference in reducing the harmful pressure points and stopping ulcers forming between the groups over a 12 month period and then run a large scale trial over many areas around the country to test this new idea in order to reduce the risk of people with diabetes developing foot ulcers.

### Who can participate?

Adults aged 18 and older who have type 1 or 2 diabetes and have a need for insoles.

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive a custom insole. Those in the second group received an unmodified insole. Participants are followed up after they receive the insole to see if there is any difference in reducing harmful pressure points and preventing ulcers from forming. A small group of participants and clinicians are interviewed about their experiences in the trial.

### What are the possible benefits and risks of participating?

There are no direct benefits with participating. The risks of taking part in this study are minimal.

As is the case with all people with a diagnosis of diabetes with a risk of foot ulceration, there is a chance of the foot ulcerating. The insoles and house shoe could also cause a rub or blister on the foot, or could make the participant feel unsteady when walking, or could cause musculoskeletal or postural pain. Additionally they may feel fatigued during the testing procedure, although rest breaks with refreshments will be offered if required.

Where is the study run from?

1. Castle Circus Health Centre (UK)
2. Newcourt House (UK)
3. Royal South Hants Hospital (UK)

When is the study starting and how long is it expected to run for?  
February 2017 to April 2020

Who is funding the study?  
National Institute for Health Research (UK)

Who is the main contact?  
Dr Richard Collings  
richard.collings@plymouth.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Richard Collings

**ORCID ID**  
<https://orcid.org/0000-0002-7048-1386>

**Contact details**  
Faculty of Health and Human Sciences  
University of Plymouth  
Peninsula Allied Health Centre  
Derriford Road  
Plymouth  
United Kingdom  
PL6 8BH

## Additional identifiers

**Protocol serial number**  
34672

## Study information

**Scientific Title**

INSTEP: Insoles to Ease Pressure. A participant and assessor blinded, randomised multi-centre parallel group feasibility trial with embedded qualitative study to compare the effectiveness of a novel instant optimised insole with a standard insole for people with diabetic neuropathy

## **Acronym**

INSTEP

## **Study objectives**

The aim of this study is to obtain the necessary information and estimate important parameters that are needed to inform the protocol development of a multi-site RCT to compare the effectiveness of a novel instant optimised insole with a standard insole for people with diabetic neuropathy.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

South West - Exeter Research Ethics Committee, 18/09/2017, ref: 17/SW/0169

## **Primary study design**

Interventional

## **Study design**

Randomised; Both; Design type: Treatment, Prevention, Device, Qualitative

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Specialty: Musculoskeletal disorders, Primary sub-specialty: Non-pharmacological Interventions; UKCRC code/ Disease: Metabolic and Endocrine/ Diabetes mellitus, Neurological/ Other disorders of the nervous system

## **Interventions**

Participants are randomised to one of two groups. Those in the first group receive the intervention insole designed to reduce peak plantar pressure in addition to usual care (Intervention) while the participants in the other group will receive an unmodified cushioned insole in addition to usual care (Control). A minimisation procedure is used to ensure equal numbers of participants in the two groups by location; study sites and by previous ulceration status. The randomised allocations will be computer-generated.

Intervention group: Optimised custom insole in standardised house shoe with usual care.

Control group: Unmodified 3mm Poron 4000 flatbed insole in standardised house shoe with usual care.

Treatment duration: One year after provision of insoles and house shoes (provided immediately after randomisation).

Participants are followed up immediately after insole issue, three, six and 12 months after randomisation.

For the participant interviews, a purposive sampling strategy is employed to recruit participants from both the intervention and control groups to ensure a broad representation of presentations (e.g. for patients – differing activity levels, previous history of ulceration), and to account for differences in age and gender.) It is anticipated as having a mix of gender across all ranges above 18 years. The three clinicians from each site will also be interviewed.

## **Intervention Type**

Other

## **Primary outcome(s)**

1. To assess the feasibility and acceptability of the trial procedures through the 12 month trial period is measured using:
  - 1.1. Numbers of eligible participants from the target population
  - 1.2. Recruitment and retention rates of eligible participants through the trial
  - 1.3. Willingness of participants to be randomised
  - 1.4. Assess the pragmatism of delivering the insole intervention in the proposed settings by qualitative interviews
  - 1.5. Variation and fidelity in the delivery of the intervention in each. A fidelity checklist will evaluate the adherence by the treating podiatrists to the standardised protocol of intervention delivery.
  - 1.6. Completeness of data sets/outcome measures
  - 1.7. Success of the blinding by using the Bang Index

## **Key secondary outcome(s)**

1. To assess the appropriateness and performance of outcome measures, to inform the selection of primary outcome for the main RCT and refine the secondary outcomes by measuring at baseline, three months, six months and 12 month follow up:
  - 1.1. Incidence of plantar foot ulceration by using photograph status of the feet
  - 1.2. Mean Peak plantar pressure (PPP) by using F-Scan in-shoe pressure measurement
  - 1.3. Extent of participant self-foot care by using Nottingham Assessment of Functional Footcare questionnaire;
  - 1.4. Extent of participant activity as by using International Physical Activity Questionnaire
  - 1.5. Extent of participant adherence to wearing the insole and footwear by using data logger
  - 1.6. To inform a power calculation for sample size estimate for the main RCT using distributional properties and standard deviations arising from differences between the intervention and control arm

## **Completion date**

01/02/2020

## **Eligibility**

### **Key inclusion criteria**

1. Confirmed diagnosis of type 1 or 2 diabetes as confirmed by medical records
2. Aged over 18 years
3. Identified clinical need for offloading insoles by podiatrist

4. Neuropathic (sensory peripheral diabetic neuropathy)
5. Palpable pedal foot pulses
6. Able and willing to comply with all trial requirement

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**Total final enrolment**

61

**Key exclusion criteria**

1. Any other significant disease or disorder which, in the opinion of the PI, may put the participant at risk of health deterioration, such as falls, because of their involvement in the trial
2. Non healing foot ulcer at another site that requires targeted off-loading
3. Unable to walk five metres with/without walking aid
4. Unable to stand on either leg independently for 10 seconds (+/- chair aid to assist in balance)
5. Lacking capacity or unwilling to give consent
6. Already wearing existing insoles that are clinically appropriate
7. Peripheral vascular disease (non-re-constructible vascular disease as determined by arterial duplex)
8. Unwilling to wear therapeutic footwear
9. Gross foot deformity e.g. charcot foot or fixed rear foot deformity
10. Unable to provide adequate consent to undertake the trial procedures
11. Major amputation of part of the foot

**Date of first enrolment**

24/10/2017

**Date of final enrolment**

01/02/2019

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre****Castle Circus Health Centre**

Torbay and South Devon NHS Foundation Trust  
Department of Podiatry and Foot Health  
Abbey Road  
Torquay  
United Kingdom  
TQ2 5YH

**Study participating centre****Newcourt House**

Royal Devon and Exeter Foundation NHS Trust  
Podiatry Services  
Old Rydon Lane  
Exeter  
United Kingdom  
EX2 7JU

**Study participating centre****Royal South Hants Hospital**

Solent NHS Trust  
Podiatry Services  
SPA, Fanshaw Wing  
Southampton  
United Kingdom  
SO14 0YG

**Sponsor information****Organisation**

Plymouth University

**ROR**

<https://ror.org/008n7pv89>

**Funder(s)****Funder type**

Government

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

**IPD sharing plan summary**

Other

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		03/02/2023	06/02/2023	Yes	No
<a href="#">Protocol article</a>	protocol	23/03/2019	09/04/2020	Yes	No
<a href="#">Basic results</a>		08/03/2021	08/03/2021	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No