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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

Submission date
25/09/2017

Recruitment status
No longer recruiting

Registration date
09/10/2017

Overall study status
Completed

Last Edited
06/02/2023

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] 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 are 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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 procedureis 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 measure
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

Secondary outcome measures
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

Overall study start date
01/02/2017

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 79; UK Sample Size: 79

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
England

United Kingdom

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
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SPA, Fanshaw Wing
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SO14 0YG

Sponsor information

Organisation
Plymouth University

Sponsor details
University of Plymouth (Ms Pam Baxter)
Postgraduate Office, John Bull Building
Research Way
Plymouth Science Park
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United Kingdom
PL6 8BU

Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
The trial results will be submitted for publication in international, high impact, peer reviewed journals primarily relating to prevention of diabetic foot ulceration/complications. It is anticipated four papers will be submitted for publication. The intent to publish date will be approximately December 2019.

In addition a plain English summary of the trial results which will be disseminated to the public, including trial participants, via Diabetes UK and the BEUP website after analyses are complete. In addition, individual participants will be able to contact their local trial site at the end of the trial for the trial results.

Intention to publish date
01/07/2021

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?
Protocol article	protocol	23/03/2019	09/04/2020	Yes	No
Basic results		08/03/2021	08/03/2021	No	No
Results article		03/02/2023	06/02/2023	Yes	No
HRA research summary			28/06/2023	No	No