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Supply chain evaluation for foot orthotic provision in the NHS

Submission date
07/10/2015

Recruitment status
No longer recruiting

Registration date
04/11/2015

Overall study status
Completed

Last Edited
29/11/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
People living with diabetes often have to live with long-term complications of the disease. One of these complications is diabetic peripheral neuropathy, where the nerves in the arms and legs become damaged, causing them to lose sensation. People suffering from diabetic peripheral neuropathy are at much greater risk of developing problems with their feet, such as foot ulcers, because the damage to the nerves reduces sensation in the foot. It is thought that high pressure on the heel and bottom of the foot (plantar pressure) increases the risk of diabetic foot ulcers. For this reason, people with diabetic neuropathy are often prescribed specially-made insoles (orthoses) in order to reduce the pressure on the parts of the foot that usually develop ulcers. Traditionally, orthoses are made using a foot impression box to create a mold which is used to create the insole. In recent years, advances in computerised design have provided an alternative way to create orthoses. The exact structure and shape of the patient's foot is captured using a digital scanner. The scan is then used to create a specially designed mold in which to make the insole. The aim of this study is to compare the effectiveness of orthoses created using these two methods.

Who can participate?
Diabetic adults with sensory neuropathy who require specially made footwear.

What does the study involve?
Participants are randomly allocated to one of two groups who receive orthoses to wear inside their specialised footwear. Those in the first group are provided with traditionally made orthoses to wear for the study period. Those in the second group are provided with orthoses which have been designed using a computer, to create a personalised insole using a specially designed mold (milling). Every month, patients are interviewed over the telephone to give their views on the insoles that they have been given. Three and six months after receiving their insoles, participants are asked to attend follow up appointments so that foot pressures can be assessed.

What are the possible benefits and risks of participating?
There are no direct benefits of taking part in this study, although it will provide information that can be used to help improve the design of insoles using in the NHS. There are no risks of participating in the study.

Where is the study run from?
Royal Blackburn Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2015 to November 2016

Who is funding the study?
Technology Strategy Board (UK)

Who is the main contact?
Dr Daniel Parker

Contact information

Type(s)
Scientific

Contact name
Dr Daniel Parker

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Randomised controlled trial comparing the efficacy of foot orthoses produced by traditional and digital design processes, to reduce pressure and assess the impact on clinical practice

Study objectives
Milled orthoses are at least effective as the comparator orthoses in terms of pressure relief, but are expected to be more effective in terms of patient and organisational benefits.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Salford ethics review panels, 29/10/2015, ref: HSCR15-89
2. NRES Committee Yorkshire & The Humber - South Yorkshire, 27/10/2015, REC ref: 15-YH-0392

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Diabetes

Interventions
Participants are randomly allocated to one of two groups using computerised block randomisation.

Group 1: Traditional Design and Manufacture Process:
The geometry of the orthotic is determined by an impression box taken in clinic. The clinician will generate a descriptive prescription for the foot orthotic, including the position of any additions and a description of the materials to be used for each component. The impression box and prescription will be posted or collected to the manufacturer for production. A plaster cast of the foot is then produced. EVA material will be heat formed to the cast and additions will be added manually to match the prescription. This will then be posted back to the clinic for fitting. EVA shells will primarily be made of Low to Medium Density (20 -40 Shore A) hardness with additional features including; varied hardness forefoot sections, cut outs, cut and fills and metatarsal bars material density used in additions will vary dependent on individual requirements. Top covers may be used where multiple additions are included.

Group 2: EVA Milled:
The upper surface will be based on unmodified shape of the plantar surface of the foot, captured using a digital scan of the patient's foot. The scan will be taken with the foot plantargrade and participant sat with both legs straight (tibia aligned) and a normal (for that participant) distance apart. The geometry of the other three orthotic surfaces will be as per a template orthotic within the iCustom design tools. The clinician will adapt the digital orthotic design to allow positioning of additions. The description of materials to be used will be recorded in the participant design notes. Digital designs will be sent electronically to UoS for production. The orthotic will be made using milling processes from a block of EVA in the range Shore A 20-40 and additions or top covers will be applied manually.

Participants attend clinical reviews at 5 months and 8 months after enrollment.

Intervention Type
Other

Primary outcome measure
Plantar pressure will be measured using an in shoe plantar pressure system which captures data concerning the distribution of weight across the bottom of the foot whilst wearing the orthotic insoles at baseline, 1, 2, 5 and 8 months.

Secondary outcome measures
1. Patient outcomes measured using validated questionnaires (EQ5D, ICECAP, FHSQ) at months 0, 1, 2, 5 and 8.
2. Compliance measured via telephone check-ups at months 3, 4, 5, 6, 7 and 8
3. Organisational outcomes measured using service data (number of appointments, number of foot wear and orthotic products supplied) at months 0 - 8
4. Service use data measured via a clinical service receipt inventory at months, 0 - 8

Overall study start date
15/08/2015

Completion date
30/11/2016

Eligibility

Key inclusion criteria
1. Aged between 40 and 85 years
2. Have diabetes diagnosed by a medical practitioner
3. Have modular or bespoke (non standard) footwear provided by the orthotics department
4. Have all normal foot structures present
5. Be able to walk without a stick for 100 metres
6. Have sensory neuropathy as assessed by 10mg monofilament and vibratory perception at 3 of 10 sites on the foot and ankle
7. Have detectable pulse in foot and ankle (palpation or Doppler)
8. Must be capable of providing informed consent to participate

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Total final enrolment
57

Key exclusion criteria
1. Have had prior foot or ankle surgery
2. Have had prior major injuries to lower limb (e.g. fractures requiring internal fixation, skin grafts)
3. Have prior or active chronic foot or leg ulceration and without episode of ulceration within last 2 years.
4. Require heel pressure reduction intervention
5. Have had prescription foot orthoses via the orthotics department in the last 12 months
6. Co-morbidities (ischemia, renal, charcot arthorpathy)

Date of first enrolment
15/10/2015

Date of final enrolment
31/03/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Sponsor information

Organisation

University of Salford

Sponsor details
The Crescent
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Sponsor type
University/education

ROR
https://ror.org/01tmqtf75

Funder(s)

Funder type
Industry

Funder Name
Technology Strategy Board

Alternative Name(s)
TSB

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
It is expected that a minimum of one research paper and one conference proceeding will be published following the completion of this work. The work will be disseminated within the East Lancashire NHS Trust. The outcomes of the study will also be used as a demonstration of the orthotic techniques available for dissemination to other NHS Trusts.

Intention to publish date
01/01/2017

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/01/2019	16/01/2019	Yes	No