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The clinical and cost effectiveness of footwear and orthotic therapy in the management of the neuropathic diabetic foot - a single blind randomised controlled trial

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
29/03/2012

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0184175869

Study information

Scientific Title

Study objectives
To determine whether therapeutic shoes used with 2 types of inserts reduce peak pressure in the at-risk diabetic foot, and to determine which of the orthotics is most effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 29 July 2008:
Ethical approval was granted by Cornwall and Plymouth Research Ethics Committee on 24/01 /2006, prior to the commencement of recruitment.

Study design
Single blind randomised controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

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
Nutritional, Metabolic, Endocrine: Diabetes

Interventions
The participants will be taken from both referrals and the existing caseload of the North and East Cornwall PCT Podiatry Service and Plymouth PCT podiatry service. Each participant will be required to complete a questionnaire and sign a consent form before taking part in the study. Each participant will receive a diabetic assessment of the lower limb to determine if they present with an increased risk of foot ulceration. Identification of the increased-risk foot include

a neurological foot assessment. Each participant will be randomly assigned to one of two groups:
Group 1 will receive 2 pairs of orthopaedic shoes and a custom made moulded insert
Group 2 will receive 2 pairs of orthopaedic shoes and inlay

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Plantar peak pressure for the entire plantar surface during the stance phase of gait.

Secondary outcome measures
Added 29 July 2008:
1. Forefoot pressure time integral
2. Total contact area
3. Rate of forefoot loading
4. Duration of load as a percentage of stance
5. Perceived foot health
6. Quality of life
7. Cost

Overall study start date
03/03/2006

Completion date
02/03/2008

Eligibility

Key inclusion criteria
1. The subject must be diagnosed as type I or II diabetic
2. The subject must be identified as neuropathic and at risk of ulceration
3. The subject must not currently be suffering from any lower limb vascular or neuropathic ulceration identified by scoring Grade 0 on the Wagner classification for foot ulcer
4. The subject must be ambulant. Must be able to walk a minimum of approximately 10 metres unaided
5. The subject must be willing to comply with the requirements of the study

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants

Sample size estimate n=130. 65 participants in each group.

Key exclusion criteria
1. Subjects with current ulceration or recently healed less than 6 months prior to enrolling onto the study (as the focus of the study is preventative ulcer management rather than treatment)
2. Subjects with severe fixed midfoot or rearfoot deformity ie Charcot joint (subjects would be unsuitable for prefabricated insoles and non-bespoke footwear)
3. Subjects with a history of bone and joint surgery of the lower limb including amputation (could lead to alteration in gait kinetics and may not be suitable for non bespoke insoles and footwear)
4. Subjects lacking the ability to comprehend simple instructions and comply with the study protocols and procedures (including those not able to read printed English)
5. Allied Health Professional students as they may be considered to have a dependant relationship with the investigator
6. Subjects diagnosed as neuropathic caused by pathology other than diabetes

Date of first enrolment
03/03/2006

Date of final enrolment
02/03/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
FF21 Peninsula Allied Health Centre
Plymouth
United Kingdom
PL6 9BH

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom

SW1A 2NL
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Plymouth Primary Care Trust - Exeter PCT (UK) NHS R&D Support Funding

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	systematic review	01/01/2011		Yes	No