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Prevention of foot ulcer recurrence in diabetes patients using plantar pressure biofeedback

Submission date
04/10/2013

Recruitment status
No longer recruiting

Registration date
04/10/2013

Overall study status
Completed

Last Edited
20/04/2021

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Some people with diabetes may develop a wound on their feet known as an ulcer. People with diabetes and a loss of sensation in their feet (known as peripheral neuropathy) are at particularly high risk of developing a foot ulcer because they have lost the ability to feel pain and other sensory information. Patients therefore have no means of knowing when damage is being done, leading to high pressure on the feet. This study uses a system to measure the pressure on the feet and provide this information to a wristwatch worn by the participant. If particularly high pressures are measured on the feet, the wristwatch will alert the participant and provide information to try to reduce these pressures. It is hoped that using this new technology will reduce the risk of foot ulcers in people with diabetes.

Who can participate?
People over the age of 18 with diabetes, neuropathy and a previous history of foot ulcers may participate in the study, although any patients with a current foot ulcer will not be eligible. Patients must be able to walk independently for around 100 metres.

What does the study involve?
Participants are randomly allocated to one of two groups. The intervention group wear very thin insole sensors underneath existing insoles inside their shoes which measure foot pressures. A wristwatch is also supplied which provides information to participants about high foot pressures and advice about how to reduce these pressures when they occur. The other group (the control group) have exactly the same as the intervention group, but the wristwatch does not provide any information and advice to participants. Participants need to wear the sensors in their shoes and the wristwatch for 18 months and are seen each month to check that the system is working properly, to examine their feet to check for a foot ulcer and to take some other simple measures such as the temperature of their feet. Participants feet are tested for nerve damage at the start of the study and again after 6, 12 and 18 months. Tests to assess the blood supply to their feet are done by measuring the blood pressure at the arm and ankle. These tests are carried out at the beginning and end of the study.

What are the possible benefits and risks of participating?
It is hoped that using this system will reduce the risk of developing a foot ulcer. Also, if

participants complete the study period (or leave the study due to a foot ulcer) they will be able to keep this system. They will also receive a monthly foot examination, which is in addition to the routine yearly examination. The researchers do not expect any risks associated with taking part in this study. The only small possible risk is that by looking at the information on the wristwatch while walking participants may become distracted, which may increase the risk of bumping into something/somebody, or tripping over something.

Where is the study run from?
This study is run from a number of sites in Manchester and the North West of the UK such as the Diabetes Centre at the Manchester Royal Infirmary, Chorley and South Ribble Hospital and the Manchester Metropolitan University.

When is the study starting and how long is it expected to run for?
November 2013 to October 2017

Who is funding the study?
Diabetes UK

Who is the main contact?
Prof. Neil Reeves
N.Reeves@mmu.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Neil Reeves

Contact details
IRM Research Institute
John Dalton Building
Chester Street
Manchester
United Kingdom
M1 5GD
-
N.Reeves@mmu.ac.uk

Additional identifiers

Protocol serial number
15186

Study information

Scientific Title
Prevention of foot ulcer recurrence in diabetes patients using plantar pressure biofeedback: a randomised controlled trial

Study objectives
The aim of this study is to prevent foot ulcers in people with diabetes and a history of foot ulceration. A system will be used that measures the pressure applied under the feet and provides information and advice to the patient if the pressure is considered to be too high. Patients with diabetes will be randomised to one of two groups: 1. an intervention group and 2. a control group. The intervention group will wear sensors in their shoes and receive information and advice on their foot pressures if they become too high. The control group will wear sensors in their shoes, but will not receive any information or advice on their foot pressures. Patients will be followed over a period of 18 months where all feet will be closely monitored for the development of an ulcer. If patients in either group develop a foot ulcer they will leave the study to be treated appropriately.

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/NW/0649; First MREC approval date 17/09/2013

Study design
Randomised; Interventional; Design type: Prevention

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Topic: Diabetes Research Network; Subtopic: Both; Disease: Neuropathy, Diabetic foot

Interventions
Once patients are recruited to the study they will be randomly assigned to one of two groups using random number generating software (1 - intervention or 2 - control):
1. Intervention (biofeedback) group, wearing in-shoe pressure sensors which provide feedback alerts (relating to high plantar pressures) and offloading guidance to a watch display for the prevention of a diabetic foot ulcer.
2. Control group, wearing in-shoe pressure sensors that measure foot pressures and store this information within the wristwatch, but do not provide any form of feedback to the patient.
Both groups would receive the same, unaltered standard clinical care including podiatry assessment and treatment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Foot ulceration. The feet will be checked for ulceration every month for 18 months.

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/10/2017

Eligibility

Key inclusion criteria
1. Diagnosed with Type 1 or 2 diabetes
2. A history of previous ulceration on the weight-bearing surface of the foot
3. Presence of neuropathy (defined by any loss of sensation)
4. Ability to walk independently for approx. 100 metres (i.e., without use of wheelchair, walking stick or personal assistance)
5. Aged >18 years
6. Able to understand all of the study requirements and have a life expectancy greater than the study duration
Target Gender: Male & Female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
58

Key exclusion criteria
1. Active foot ulcer
2. In-shoe orthotics consisting of non-compressible materials
3. Presence of severe ischaemia for either foot defined by complete absence of foot pulses and ankle-brachial pressure index <0.6
4. Lower limb amputation affecting the ability to walk approx. 100 metres
5. Dementia, uncorrected visual or psychological impairment
6. Psychiatric illnesses or social situations that would limit compliance with the study
7. Inner ear pathology, or other serious underlying balance dysfunction
8. Significant cardiopulmonary or other systemic disease limiting the patient's ability to walk approx. 100 metres unaided

9. Current participation in another clinical investigation of a medical device or a drug, or participation in such a study within 30 days prior to study enrolment
10. Body Mass Index (BMI) >40

Date of first enrolment
07/11/2013

Date of final enrolment
30/11/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
IRM Research Institute
Manchester
United Kingdom
M1 5GD

Sponsor information

Organisation
Manchester Metropolitan University (UK)

ROR
https://ror.org/02hstj355

Funder(s)

Funder type
Charity

Funder Name
Diabetes UK (UK); Grant Codes: 12/0004565

Alternative Name(s)
The British Diabetic Association, DIABETES UK LIMITED, British Diabetic Association

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available, as participant consent to allow data sharing was not sought.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	of Diabetes	01/10/2019	20/04/2021	Yes	No
Abstract results		02/10/2018	24/06/2019	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes