

# SSHOES Diabetic Footwear

<b>Submission date</b> 19/08/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 19/08/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/04/2017	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Stephen Preece

### Contact details

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M6 6PU

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

8619

## Study information

Scientific Title

A multicentre non-randomised interventional trial of diabetic footwear in the prevention of foot ulceration

**Acronym**

DRN 475

**Study objectives**

The aim of this study is to investigate the effect of four separate footwear design parameters which characterise a rocker shoe in order to develop a system which allows the best design, i.e. the one which minimises pressure, to be predicted from a simple biomechanical assessment of barefoot walking.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

North West 8 Research Ethics committee - Greater Manchester East, 05/07/2010, ref: 10/H1013 /32

**Study design**

Multicentre non-randomised interventional trial

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**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**

Topic: Diabetes Research Network; Subtopic: Both; Disease: Diabetic foot

**Interventions**

The aim is to measure in-shoe pressures in many different types of footwear in a lab for a range of patients. With this information, we want to develop a system for prescribing bespoke footwear (i.e., footwear which minimises pressure). Patients do not undergo any treatment.

Study Entry: registration only

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Foot pressure after wearing the footwear for 5 minutes under laboratory conditions

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

01/06/2010

**Completion date**

01/08/2012

## **Eligibility**

**Key inclusion criteria**

1. Have been diagnosed with diabetes at least 6 months previously (diabetic cohort only)
2. Be between 18 and 65 years, either sex
3. Be able to the University of Salford three times
4. Be able to walk for 2 - 5 minutes barefoot and in different shoes over 1.5 - 2 hours
5. Be able to understand both written and spoken English

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned sample size: 100; UK sample size: 100

**Key exclusion criteria**

1. Currently suffering with any form of ulceration or other foot condition resulting from diabetes
2. Have a major foot deformity sufficient to limit activity
3. Suffering any disorder with affects balance or mobility and/or a history of falls

**Date of first enrolment**

01/06/2010

**Date of final enrolment**

01/08/2012

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

**University of Salford**

Salford

United Kingdom

M6 6PU

# Sponsor information

## Organisation

Salford Royal NHS Foundation Trust (UK)

## Sponsor details

c/o Dr Rachel Georgiou

NHS Salford Research and Development

Clinical Sciences Building

Stott Lane

Salford

England

United Kingdom

M6 8HD

## Sponsor type

Hospital/treatment centre

## Website

<http://www.srht.nhs.uk/>

## ROR

<https://ror.org/019j78370>

# Funder(s)

## Funder type

Government

**Funder Name**

European Union (EU) (Belgium) - Seventh Framework Programme (FP7)

**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