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Effects of shoes in individuals with intermittent claudication

Submission date
09/05/2014

Recruitment status
No longer recruiting

Registration date
17/07/2014

Overall study status
Completed

Last Edited
26/05/2017

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Intermittent claudication is pain in the leg brought on by walking and is caused by poor blood flow to the muscles. It is intermittent because it only comes on with walking or exercise and goes away when you rest. In this study, we want to find out the specific effects of rocker sole shoes and orthotic designs on the walking of people with intermittent claudication. Four different types of footwear and one orthotic device will be tested. The results of this study will tell us if specific shoe features are linked to specific changes in the balance of forces at the legs during walking and to resulting changes in calf muscle activity. These results will be used to design shoes for individuals with intermittent claudication that will specifically target their calf muscle activity in order to increase their pain-free walking distance and therefore allow them to be more mobile. The same concept will be used for the design of shoes that exercise the calf muscles to improve circulation at the lower limb. Such shoes can be very important assets to the management of intermittent claudication.

Who can participate?
The study aims to recruit 40 people diagnosed with lower limb intermittent claudication and 40 healthy adults.

What does the study involve?
Participants will be walking in four different type of shoes in a random order, across a gait (walking) laboratory. The data on their gait and muscle activity are collected and analysed to see if the type of shoe has any effect on their walking.

What are the possible benefits and risks of participating?
The participants will not have any direct benefit from this study. However, the results will be used in the design of shoes for people with intermittent claudication, hence improving their quality of life in the future. During the tests there is a chance that patient participants may feel aching in their calves that they sometimes experience when they walk, but we do not expect this to occur because we will not be asking them to walk very far. Participants will be able to take frequent rests. Because the shoes we are testing are different to the ones participants usually wear they may need some time to get used to them. They will therefore be given as much time as they need to get comfortable and used to wearing the shoes. Sometimes, people can feel

unsteady in new footwear, but there are no reported risks of falls or trips in these shoes. Whilst we do not expect it to be necessary, if they prefer, a person will be able to walk close to them during the walking tests.

Where is the study run from?
We will be recruiting through an NHS clinic (Linacre centre, Wigan, UK) and healthy individuals through posters and a university volunteer database.

When is the study starting and how long is it expected to run for?
The study started in June 2014 and will run for 6 months.

Who is funding the study?
1. University of Salford (UK)
2. The Wrightington, Wigan and Leigh NHS Foundation Trust (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HSCR13/91

Study information

Scientific Title

An understanding of footwear and orthotic modifications on gait biomechanics in patients with int

Study objectives
1. Individuals with intermittent claudication walk differently to healthy counterparts and have weaker calf muscles
2. Rocker sole shoes will significantly change the gait of individuals with intermittent claudication and will decrease the work required by the calf muscles

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South East Coast - Brighton and Sussex, 28/03/2014, ref. 14/LO/0382

Study design
Randomised case control study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Peripheral arterial disease (PAD)

Interventions
Subjects will perform trials in a custom standard shoe, four rocker sole shoes (3 curve rocker, 2 curve rocker, 1 curve rocker, MBT shoe) and a standard ankle foot orthosis.

Participants with PAD will be walking in a control shoe, a 2 three-curve rocker sole shoes, a 2 curve rocker sole shoe, and in a shoe-orthotic combination with all three shoes. The orthotic is a regular solid AFO set at 90 degrees. The sequence in which they will wear the interventions will be pre-randomised using statistical software (minitab).The testing will take place at the University of Salford podiatry gait laboratory.
With regard to outcome measures, data will be collected using a camera capture system (Qualysis), force plates and wired EMG system (Norax) as participants walk across the room. All data will be collected in a single 3-hour session. This data will be processed using Visual 3D software, followed by matlab processing. Statistical analysis will be done using Minitab software.

Healthy participants will only walk in the control shoe. The same data will be collected on them using the same systems. This is a shorter, 1-hour session.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. External ankle moment
2. EMG muscle activation

Secondary outcome measures
1. External knee flexion moment
2. Eternal hip flexion moment

Overall study start date
16/09/2013

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Participants admitted to the study will range between the ages of 50 and 75.
2. Participants must have a formal diagnosis of intermittent claudication of at least 3 months confirmed by a consultant vascular surgeon. This diagnosis will be derived using colour-flow duplex scan, medical history and examination, and absence or reduction in foot pulses, an ankle brachial pressure index (ABPI) of less than 0.8.
3. Participants must be able to walk a minimum of 100 m or perform 2 minutes of continuous walking unaided.
4. Healthy participants must be aged 50 or over.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
40 individuals with intermittent claudication and 40 healthy counterparts will be recruited

Key exclusion criteria
1. Active or a prior history of foot ulcers
2. Significant foot deformities necessitating use of foot orthoses
3. Self-reported complete neuropathy in their feet (a reported lack of diabetes will be verified through a foot sensation test)

4. Surgery in the previous 6 months
5. Pain in their lower limbs or back with a cause unrelated to PAD/IC
6. Painful knee, ankle or hip osteoarthritis
7. Total reliance on walking aids
8. Prior lower limb joint replacement
9. Morbidly obese (BMI>35). Marker placement relies on identification of joint centres and bony landmarks and these must be easily palpated by hand.
10. Healthy participants must not have any of the following: significant pain in the legs when walking, prior injury to the legs or spine, diabetes, foot deformities, prior joint replacement or major orthopaedic surgery.

Date of first enrolment
15/06/2014

Date of final enrolment
30/11/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Salford
School of Health Sciences
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Sponsor information

Organisation
University of Salford (UK)

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Sponsor type
University/education

ROR
https://ror.org/01tmqtf75

Funder(s)

Funder type
University/education

Funder Name
University of Salford (UK)

Funder Name
The Wrightington, Wigan and Leigh NHS Foundation Trust (UK); Ref: HSCR13/91

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
30/06/2018

Individual participant data (IPD) sharing plan
The data sharing plans have not been finalised and would require a revision to ethical approval if at a participant level.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V4.1	13/08/2015	26/05/2017	No	Yes
HRA research summary			28/06/2023	No	No