

The biomechanical effect of rocker shoes in people with knee osteoarthritis

Submission date 17/11/2015	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 23/11/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 16/08/2022	Condition category Musculoskeletal Diseases	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Knee osteoarthritis (OA) is a condition that causes the knees to become painful and stiff. It is strongly affected by the way in which the knee joint is loaded during activities (i.e., the force put on the knee joint). Previous studies have found that footwear which alters the loading at the knee joint can reduce the pain. However, to date there has been relatively little research investigating the potential effects of rocker shoes. These shoes have a curved sole and are designed to rock the foot forward when walking. This rocking action may change the way in which the muscles of the leg activate and this may bring about a corresponding change in the way the joint is loaded. Before undertaking a large study, it is important to understand the effects of rocker footwear. Therefore, this study has been designed to find out how this type of footwear changes muscle activation patterns and how it may impact on joint loading in both individuals with knee osteoarthritis and healthy volunteers.

Who can participate?

Knee osteoarthritis patients and healthy volunteers aged between 40-85.

What does the study involve?

Each participant attends a single laboratory testing session at the University of Salford, during which they will wear different types of footwear (i.e., rocker footwear and a flexible OA shoe) whilst muscle activation and 3D motion data is collected.

What are the possible benefits and risks of participating?

Participants will experience different types of footwear, but we do not expect this to provide any significant benefits to participants. We are able to provide participants with travel expenses for participating. There are no risks of participating.

Where is the study run from?

University of Salford (UK)

When is the study starting and how long is it expected to run for?

November 2015 to November 2017

Who is funding the study?
University of Salford (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Protocol v2

Study information

Scientific Title
The biomechanical effect of rocker shoes in people with knee osteoarthritis: a randomised cross-over trial

Study objectives
This study will therefore compare the biomechanical effect of this specific design of rocker shoe, with both a flexible shoe and also a standard control shoe.

Ethics approval required
Old ethics approval format

Ethics approval(s)
UK NHS ethics committee of East Midlands - Derby, 17/11/2015, REC ref: 15/EM/0502

Primary study design

Interventional

Study design

Randomised cross-over trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Knee osteoarthritis

Interventions

Single-centre trial in which we plan to investigate the biomechanical effects of different footwear. This will be achieved with a laboratory cross-over study at the University of Salford, during which participants will wear the different types of footwear (rocker footwear and a flexible OA shoe) during a single testing session whilst biomechanical data (muscle activation and 3D motion) is collected.

Intervention Type

Other

Primary outcome(s)

Muscular co-contraction of the quadriceps and hamstrings and the quadriceps and gastrocnemius, derived from electromyography (EMG) data collected from the specified muscles during walking

Key secondary outcome(s)

1. The knee extensor moment outcome calculated from force and kinematic (3D motion) data collected during walking
2. The centre of mass position derived from full-body 3D motion data during walking

Completion date

23/11/2017

Eligibility

Key inclusion criteria

1. Age range 40-85 (upper age limit due to the amount of walking involved in the study)
2. Ability to stand and walk independently
3. Speak and understand written English
4. Ability to walk without any walk assistive for at least 250 m
5. Clinical diagnosis of knee OA according to American College of Rheumatology (ACR) (Altman et al. 1986) (if they are a participant with knee OA)
6. Pain for at least 6 months' duration (if they are a participant with knee OA)
7. Pain or difficulty in rising from sitting and/or climbing stairs (if they are a participant with knee OA)

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Complex pain conditions such as diabetic neuropathic pain, fibromyalgia
2. Have had previous surgery to the lower limb
3. BMI >33 since it is not possible to perform accurate measurements on individuals with excess adipose tissue
4. Lower limb arthroplasty
5. Any systemic inflammatory disorders, such as rheumatoid arthritis
6. Any balance disorders which may increase the risk of a fall

Date of first enrolment

23/11/2015

Date of final enrolment

23/11/2017

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre**University of Salford**

Centre for Health Sciences Research

Blatchford Building

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Salford

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Sponsor information**Organisation**

University of Salford (UK)

ROR

<https://ror.org/01tmqtf75>

Funder(s)

Funder type

University/education

Funder Name

University of Salford (UK)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Thesis results		18/12/2018	16/08/2022	No	No