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The biomechanical effect of rocker shoes in people with knee osteoarthritis

Submission date
17/11/2015

Recruitment status
No longer recruiting

Registration date
23/11/2015

Overall study status
Completed

Last Edited
16/08/2022

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised cross-over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

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
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 measure
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

Secondary outcome measures
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

Overall study start date
23/11/2015

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

Age group
Adult

Sex
Both

Target number of participants
30 with OA and 30 healthy volunteers

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
England

United Kingdom

Study participating centre
University of Salford
Centre for Health Sciences Research
Blatchford Building
University of Salford
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Sponsor information

Organisation
University of Salford (UK)

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Allerton Building
University of Salford
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Sponsor type
Research organisation

ROR
https://ror.org/01tmqtf75

Funder(s)

Funder type
University/education

Funder Name
University of Salford (UK)

Results and Publications

Publication and dissemination plan
The results will be submitted for publication in biomechanics and osteoarthritis journals

Intention to publish date
14/05/2022

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?
Thesis results		18/12/2018	16/08/2022	No	No
HRA research summary			28/06/2023	No	No