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Tailored lateral wedge insoles in medial knee osteoarthritis

Submission date
08/08/2019

Recruitment status
No longer recruiting

Registration date
05/10/2019

Overall study status
Completed

Last Edited
03/09/2021

Condition category
Musculoskeletal Diseases

[_] 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 degenerative joint disease with no known cure that is characterized by joint pain and dysfunction. One of the factors for the progress of OA is the increased physical forces causing damage in the joint. Knee malalignment is a key factor for the progress to more severe disease. Traditional treatments have shown poor long-term effectiveness. Biomechanical interventions are advised in order to provide a better alignment and a redistribution of mechanical forces. Lateral wedge insoles are effective on external knee adduction moment reduction. However, some patients do not respond to treatment. The aim of this study is to find out whether tailored lateral wedge insoles worn daily for 12 weeks can improve the symptoms of patients with medial knee OA.

Who can participate?
Patients aged 50 to 80 with medial knee OA

What does the study involve?
Participants are randomly allocated to use either neutral insoles or tailored lateral wedge insoles to put inside their own shoe and use for 3 months. Knee function and pain are assessed at the start of the study and after 3 months.

What are the possible benefits and risks of participating?
Patients may benefit from reduced symptoms such as pain or knee edema. There are no known risks with the use of insoles, only foot discomfort.

Where is the study run from?
University of Porto (Portugal)

When is the study starting and how long is it expected to run for?
May 2017 to October 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Vitor Ferreira
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1A

Study information

Scientific Title
Tailored lateral wedge insoles in medial knee osteoarthritis

Study objectives
An adjusted degree of lateral wedge insoles compared with control insoles worn daily for 12 weeks improve symptoms and biomechanical parameters in people with medial knee OA.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 24/03/2017, Ethics Committee of the Faculty of Sports of the University of Porto, and Ethics Committee of local hospitals (Faculdade de Desporto da Universidade do Porto, R. Dr. Plácido da Costa 91, 4200-450 Porto, Portugal; Tel: +351 (0)22 04 25 200; Email: cefade@fade.up.pt), Process CEFADE 10.2016

Study design
Single-centre randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Medial knee osteoarthritis

Interventions
The randomization sequence was generated using specific software by an independent collaborator not directly involved in assessment of participants.

Participants in the experimental group received a pair of customized lateral wedge insoles to put inside their own shoe and use for 3 months. The lateral wedge insoles were custom made with a pronating wedge posterior long. The degree of the lateral wedge insole in the experimental group was customized to each participant by the acute effects on initial biomechanical measurements.

The participants of the control group received a pair of neutral lateral wedge insoles.

Intervention Type
Other

Primary outcome measure
First peak external knee adduction moment measured by gait analysis at baseline and 12 weeks

Secondary outcome measures
1. Pain measured with visual analog scale at baseline and 12 weeks
2. Pain, other symptoms, function in daily living, function in sport and recreation, and knee-related quality of life, measured using the Knee Injury and Osteoarthritis Outcome Score (KOOS) questionnaire at baseline and 12 weeks
3. Physical function assessed using physical tests (30s chair stand test; 40m fast-paced walk test; stair climb test) at baseline and 12 weeks

Overall study start date
01/05/2017

Completion date
31/10/2019

Eligibility

Key inclusion criteria
1. Diagnosis of knee OA made according to the clinic and radiographic criteria established by the American College of Rheumatology. This comprises medial knee pain, radiographic osteophyte in the medial joint space of the knee and morning stiffness lasting 30 min and/or crepitus during motion
2. Specific radiographic inclusion criteria are Kellgren & Lawrence grade 2 or 3 on a full-length anteroposterior radiograph
3. Age 50 and < 80 years old
4. Medial knee pain in the past week of ≥3 on Visual Analog Scale

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Total final enrolment
38

Key exclusion criteria
1. Symptomatic evidence of lateral compartment
2. Patellofemoral OA
3. Knee surgery within the past six months
4. Systemic arthritic conditions
5. Corticosteroid injection within the previous six weeks
6. Body mass index above 35 (difficult to accurately place motion capture markers)
7. Any other condition affecting lower limb function

Date of first enrolment
01/05/2018

Date of final enrolment
01/08/2019

Locations

Countries of recruitment
Portugal

Study participating centre
University of Porto
Porto Biomechanics Laboratory (LABIOMEP)
R. Dr. Plácido da Costa 91
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Sponsor information

Organisation
Faculdade de Desporto da Universidade do Porto

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Sponsor type
University/education

ROR
https://ror.org/043pwc612

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The protocol is not published and/or available online. Planned publication of the results in peer-reviewed journals.

Intention to publish date
01/01/2020

Individual participant data (IPD) sharing plan
All data collected is confidential. No personal identification will be made in any publication of the results of this study. Group results will be presented later, but the participant will never be individually identified. Data access requests may be made to Vitor Ferreira (v.ferreira@ua.pt), but only group statistics, up to a maximum of 2 years after the end of the study.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/03/2021	03/09/2021	Yes	No