

The effectiveness of shoes and insoles on the loading at the knee in subjects with knee osteoarthritis

Submission date
28/05/2010

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
28/05/2010

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
21/09/2016

Condition category
Musculoskeletal Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

7883

Study information

Scientific Title

The effectiveness of Shoes and Insoles on the Loading at the Knee in subjects with knee osteoarthritis: single centre randomised interventional treatment trial

Acronym

SILK

Study objectives

The aim of this study is to investigate the role of different shoes and insoles in the treatment of medial tibiofemoral osteoarthritis of the knee joint.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Tameside (now Northwest 8) MREC, 18/08/2010, ref: 09/H103/51

Study design

Single centre randomised interventional treatment 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

Topic: Musculoskeletal; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions

Patients attend the gait laboratory for one visit that lasts approximately 2-3 hours when they complete the questionnaires and the following gait lab assessments are undertaken, there is no followup.

1. Static Pedography
2. Dynamic Walking
3. Photographs
4. 3-D image obtained

All participants are then treated with different therapeutic insoles/shoes reported to lower the adduction moment. The order in which each participant receives each treatment is randomised prior to the visit.

The interventions are:

1. Barefoot walking
2. Mobility shoe designed to mimic barefoot walking
3. Control shoe on its own
4. Control shoe with unsupported lateral wedge
5. Control shoe with salford wedge

While undertaking each intervention walking is assessed and pain and comfort scores are completed.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. The external knee adduction moment change during the trials will be recorded for all conditions to allow the investigators to determine which intervention has the best reduction in this measure. All sections of the knee adduction moment curve (different peaks) and also the knee adduction angular impulse (the area under the curve) will be assessed for differences between conditions.

2. Patient-perceived global change in pain:

The patient-perceived global change in pain scores during the trials will be analysed on a 5 point likert scale with scores of 1 - much worse, 2 - slightly worse, 3 - No change, 4 - slightly better and 5 - much better (Hinman et al, 2008).

3. Comfort rating questionnaire:

The differences in the overall comfort (Mundermann et al, 2002) of the footwear and the likelihood of using the intervention will be assessed in the different conditions. This is important as it will inform whether the intervention would be generalisable to the whole population and ensure compliance in future studies.

Secondary outcome measures

1. Foot characteristics:

Each of the participants will be given a rating of their foot posture to allow subsequent correlation with the changes seen in the knee adduction moment data.

2. Foot pressure pattern:

The movement of the centre of pressure will be examined to examine each of the interventions characteristics in this pattern. In addition, the foot pressure pattern will be split into seven masks which represent different areas of the foot to examine the peak pressures during the tests.

Overall study start date

31/08/2009

Completion date

31/08/2010

Eligibility

Key inclusion criteria

To define medial knee OA, a patient must meet all of the following:

1. Pain with walking (using Knee injury and Osteoarthritis Outcome Score [KOOS] pain question, they need to have at least mild pain walking on a flat surface) - clinical diagnosis by qualified clinician
2. On anteroposterior (AP) or posteroanterior (PA) view x-ray (weight bearing, if possible), they need to have definite medial narrowing and NOT lateral narrowing and evidence (osteophyte+ or definite sclerosis) of OA - radiographic diagnosis. Confirmation of radiological diagnosis will be performed by Dr Charles Hutchinson to ensure consistency in x-ray classification less than grade 4 of the Kellgren Lawrence (KL) scale.
3. Medial tenderness either by their own indication that this is where they have pain or by examination showing tenderness at the medial TF joint line - clinical diagnosis by qualified clinician
4. They are able to walk for 100 metres nonstop - participant response
5. Aged 45 years or older, either sex

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned sample size: 50

Key exclusion criteria

1. Pain is more localised to the patellofemoral joint on examination, rather than medial joint line
2. Have tricompartmental knee osteoarthritis or grade 4 medial tibiofemoral osteoarthritis on the Kellgren Lawrence scale
3. A history of high tibial osteotomy or other realignment surgery
4. Total knee replacement on the affected side
5. Any foot and ankle problems that will contraindicate the use of the footwear load

Date of first enrolment

31/08/2009

Date of final enrolment

31/08/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Manchester

Manchester

United Kingdom

M13 9PT

Sponsor information

Organisation

University of Salford (UK)

Sponsor details

Arthritis Research Campaign

Copeman House

St. Marys Court

St. Marys Gate

Chesterfield

England

United Kingdom

S41 7TD

Sponsor type

University/education

Website

<http://www.salford.ac.uk/>

ROR

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

Funder(s)

Funder type

Charity

Funder Name

Arthritic Research Campaign (ARC) (UK)

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

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2013		Yes	No
Results article	results	01/09/2014		Yes	No
Results article	results	01/08/2015		Yes	No
Results article	results	01/11/2015		Yes	No