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

Submission date	Recruitment status	[ ] Prospectively registered
28/05/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/09/2016	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 with 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
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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