

# The effectiveness of a lateral wedge insole on osteoarthritis pain, activity level and joint loading

<b>Submission date</b> 19/09/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 29/06/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/10/2020	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Osteoarthritis (OA) is a condition that causes the joints to become painful and stiff. People with knee OA suffer from pain during normal activities such as walking, standing or climbing stairs, so they reduce their overall activity in order to minimise the pain. Using lateral wedge insoles in their shoes can reduce patients' pain by decreasing the weight which is transmitted through their knee joint. The aim of the study is to find out whether a lateral wedged insole improves activity levels in patients with medial knee OA.

### Who can participate?

Participants aged 40-85 suffering from OA and on the waiting list for surgery.

### What does the study involve?

Participants with knee OA will be randomly allocated into two groups, to wear either lateral wedged insoles or neutral insoles for six weeks. Knee loading, level of physical activity, knee pain, physical function and balance will be measured.

### What are the possible benefits and risks of participate?

There will be no immediate direct benefits to those taking part as the result will help future practice with insoles. However, wearing insoles for six weeks may decrease knee pain and increase comfort when walking. There are no risks with using insoles or during the study. Using the activPAL device (to monitor the level of physical activity) is completely safe as this has been used many times previously and it is comfortable to wear for the participants.

### Where is the study run from?

The study will be performed in the gait laboratory at the University of Salford (UK).

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

From May 2015 until June 2016.

Who is funding the study?

1. University of Salford (UK)
2. King Saud Medical City (Saudi Arabia)

Who is the main contact?

Professor Richard Jones, r.k.jones@salford.ac.uk

Mr Yasser Althebaity, y.m.althebaity@edu.salford.ac.uk

## Contact information

### Type(s)

Scientific

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

062015

## Study information

### Scientific Title

The effectiveness of a lateral Wedge insole on osteoarthritis Pain, Activity level and joint Loading: a pilot study

### Acronym

WPAL Study

### Study objectives

The external knee adduction moment (knee loading) will decrease in the group using the lateral wedged insole. Whereas, level of physical activity, knee pain, dynamic balance, and physical

function will improve in the group using the lateral wedged insole. In addition, it is hypothesised that reduction in knee loading will lead to a corresponding increase in activity level in comparison to the comparator group.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

1. Ethical Approval Panel, the University of Salford, 04/06/2014, ref: HSCR14/24
2. NHS ethics approval: not provided at time of registration.

### **Study design**

Randomised pilot study

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please contact the principle investigator to request a participant information sheet.

### **Health condition(s) or problem(s) studied**

Medial knee osteoarthritis

### **Interventions**

Patients are randomised to two groups: lateral wedged insole group, and neutral insole group. Participants will wear those insoles for six weeks

### **Intervention Type**

Device

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

Lateral wedge insole

### **Primary outcome measure**

1. Level of physical activity
2. External knee adduction moment (EKAM)
3. Pain level

Outcomes will be measured in four different specific period of time (pre- intervention, baseline, during intervention, post-intervention) to find out any change in these outcomes compare to the baselines findings.

### **Secondary outcome measures**

1. Dynamic balance
2. Knee injury and Osteoarthritis Outcome Score (KOOS) other items
3. Physical Activity Score for the Elderly (PASE)
4. Aggregated Locomotor Function (ALF) score
5. 12-item Short-Form Health Survey (SF-12)

### **Overall study start date**

01/05/2015

### **Completion date**

30/06/2016

## **Eligibility**

### **Key inclusion criteria**

1. Age 40-85
2. Pain with walking.
3. Participants have been diagnosed with mild-moderate medial knee OA by GP based on the clinical and radiographic criteria
4. On AP or PA view x-ray (weight bearing, if possible) within the last 2 years of screening. Therefore, for a patient to be eligible on x-ray they must fulfil the following criteria
  - 4.1. KL grade 2 or 3 in the tibiofemoral joint (TFJ)
  - 4.2. The KL grade in the TFJ must be higher than the PFJ and cannot be equal
  - 4.3. The medial joint space narrowing score must be higher that the lateral joint space narrowing score and cannot be equal
5. Medial tenderness. Absence of PF tenderness on examination.
6. They are able to walk for 100 metres non-stop - participant response.
7. Can walk without any walking aid.

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

30 participants with medial knee OA.

### **Total final enrolment**

20

### **Key exclusion criteria**

1. A history of high tibial osteotomy or other realignment surgery or total knee replacement on the affected side
2. Knee Arthroscopy with the last 6 months
3. Intra-articular injection into the treatment knee in the last 3 months.
4. Inflammatory arthritis including Rheumatoid Arthritis
5. Complex pain conditions such as fibromyalgia
6. Any foot and ankle problems
7. Severe coexisting medical morbidities,
8. Use, or have used, orthoses within the last 2 months.
9. BMI >35 since gait laboratory cannot perform accurate measurements.
10. Unable to walk unaided.

If the participants cannot walk for 100 metres without stopping they will also be excluded, as they may be unable to complete the full testing protocol.

**Date of first enrolment**

01/05/2015

**Date of final enrolment**

30/06/2016

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**PO36 Brian Blatchford Building**

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## Sponsor information

**Organisation**

University of Salford (UK)

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### Sponsor type

University/education

### Website

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

### ROR

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

## Funder(s)

### Funder type

University/education

### Funder Name

University of Salford (UK)

### Funder Name

King Saud Medical City (Saudi Arabia)

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

2018 results in thesis <http://usir.salford.ac.uk/id/eprint/43818/> (added 26/10/2020)

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/04/2017	26/10/2020	Yes	No