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Clinical trial of insoles for pain at the front of the knee

Submission date	Recruitment status	[ ] Prospectively registered
23/04/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
31/07/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/05/2016	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CT223

Study information

Scientific Title

A randomised controlled trial to evaluate the effectiveness of insoles to treat anterior knee (patella femoral) pain

Acronym
KP Trial

Study objectives
Knee pain remains a significant burden to a large proportion of the population. It has a multifactorial etiology and diagnosis is often non specific. Anterior knee pain (patellofemoral pain syndrome) has been described as the most prevalent disorder of the knee. The cause of the condition is not clearly understood and the cause of pain may not be the same for each person. Hence a variety of treatment regimes (devices) are employed for the treatment of the condition. Citizens are likely to seek their own approaches to managing knee pain prior whilst waiting for, or instead of, seeking advice and remedy from the health services. This trial will seek to evaluate the effectiveness of an in shoe type of orthosis in the management of anterior knee pain.

Hypothesis: a functional insole will produce greater improvements in knee pain compared to a sham control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee, University of Salford, 12/03/2008, ref: 07/054

Study design
Randomised subject-blinded single-centre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anterior knee pain

Interventions
The participants will be randomly allocated to the following two arms:
1. Arm 1: Orthaheel® regular. This is a 3/4 length insole with arch shape. It is inserted into shoes and worn daily for 12 months
2. Arm 2: Sham control insole. This is a full length 3 mm deep soft flat insole. It is inserted into shoes and worn daily for 12 months

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Knee pain
2. Knee function

The outcomes above will be measured using the following at 4 weeks:
a. VAS (scores 0-10)
b. The Kujala Anterior knee pain questionnaire

Key secondary outcome(s))
1. Use of insoles (in time)
2. Knee pain at 3, 6 and 12 months (see primary outcome measures for methods of measurement)
3. Knee function at 3, 6 and 12 months (see primary outcome measures for methods of measurement)

Completion date
31/07/2009

Eligibility

Key inclusion criteria
1. Male or female participants between the ages of 18 and 65 years old
2. Participants with self-reported anterior knee pain (pain at the front of the knee) with a minimum of 4 weeks duration
3. Participants with self-reported anterior knee pain who score at least 40 mm on a 100 mm visual analogue scale (VAS) for pain
4. Participants with self-reported anterior knee pain in the 2 days prior to recruitment
5. Participants who agree to wear the insoles provided for at least 4 hours each day and complete diary cards and postal questionnaire as required
6. Participants who give written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients must not report any acute injury to the knee at the onset of their anterior knee pain
2. Patients must not report posterior or medial/lateral knee pain or any secondary pain elsewhere in lower limb joints since the onset of anterior knee pain

3. Patients must not have any significant diagnosed musculo-skeletal disease, such as rheumatoid arthritis, diabetes or osteoarthritis of the knee or deterioration dysfunction of associated structures of the knee e.g., cartilage or any other condition associated with sensory and motor dysfunction
4. Patients must not have received or self administered treatment for the knee pain in the previous 4 weeks
5. Patients who are pregnant or breast-feeding
6. Patients who have received or self-administered treatment for the knee pain in the previous 4 weeks
7. Patients who have received corticosteroid injection therapy in the knee in the previous 3 months
8. Patients that were previously in this study
9. Patients that were in another study within the last 3 months

Date of first enrolment
28/03/2008

Date of final enrolment
31/07/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Director
Salford
United Kingdom
M6 6PU

Sponsor information

Organisation
SSL International (UK)

ROR
https://ror.org/01g87hr29

Funder(s)

Funder type

Industry

Funder Name
SSL International (UK)

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes