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# Research in Osteoarthritis in Manchester (ROAM) Brace

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 21/05/2010 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 21/05/2010 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 19/01/2015 | 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**
7137

# Study information

## Scientific Title
Patellofemoral brace treatment in patients with chronic painful patellofemoral osteoarthritis (PFOA): a single centre randomised interventional treatment trial

## Acronym
ROAM Brace

## Study objectives
This study will form the first part of an Arthritis Research UK sponsored Osteoarthritis Programme grant to develop new treatment approaches for knee OA (Research in Osteoarthritis in Manchester - ROAM). There are three studies to be done in one group of PFOA patients. This will permit us to examine three related questions:

Study 1:
In a 6-week randomised trial compared to a no brace control, does the brace lead to diminution of synovitis and BMLs and reduction of pain and are these events related?

Study 2:
We will conduct a follow-up study for those in the trial. We will address whether in those who have noted a reduction in pain with the brace, does discontinuation of the brace lead to recurrence of pain and concomitant reappearance of magnetic resonance imaging (MRI) findings?

Study 3:
We will take measurements to test the third hypothesis that severity of knee pain is more strongly related to the degree of quadriceps muscle weakness, inhibition and pain and of hip abductor weakness than MRI findings in the knee including the size of the knee effusion (capsular distension) and the predominant compartment affected by PFOA.

Pain diaries will be used to monitor pain medication usage during the trial.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Stockport REC approved on the 16th June 2009 (ref: 09/H1012/35)

## Study design
Single centre randomised interventional treatment trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
GP practice

### Study type(s)
Treatment

### Participant information sheet
Can be found at http://www.medicine.manchester.ac.uk/epidemiology/research/arc/clinicalepidemiology/roam

### Health condition(s) or problem(s) studied
Topic: Musculoskeletal, Primary Care Research Network for England; Subtopic: Not Assigned, Musculoskeletal (all Subtopics); Disease: Musculoskeletal, All Diseases

### Interventions
The Brace study is a cross over randomised controlled trial:

Patient group 1:
Receives a brace at the baseline visit for a period of twelve weeks, with checks at 6 and 12 weeks. Following this the patient is monitored for a period of 6 further weeks with no brace.

Patient group 2:
Receives no brace for the first at baseline, then is given a brace to wear at week 6 visit, for the subsequent 12 weeks (monitored at weeks 12 and 18).

Both groups are therefore monitored for 18 weeks.

Study entry: single randomisation only

### Intervention Type
Other

### Phase
Phase IV

### Primary outcome measure
VAS on nominated activity, measured at baseline, 6 weeks ,12 weeks and 18 weeks.

### Secondary outcome measures
1. Aggregated Locomotor Function, measured at baseline, 6 weeks, 12 weeks and 18 weeks
2. Hip Abduction Strength, measured at baseline, 6 weeks, 12 weeks and 18 weeks
3. Knee injury Osteoarthritis Outcome Score (KOOS), measured at baseline, 6 weeks, 12 weeks and 18 weeks
4. Quadriceps Inhibition, measured at baseline, 6 weeks, 12 weeks and 18 weeks
5. Quadriceps strength (secondary), measured at baseline, 6 weeks, 12 weeks and 18 weeks

### Overall study start date
17/08/2009

### Completion date
29/03/2013

## Eligibility

### Key inclusion criteria
1. Age 40 - 70 years, either sex
2. Radiographic evidence of Kellgren-Lawrence score 2 or 3 predominating in the PF joint
3. Evidence of a bone marrow lesion on a clinical MR scan, or documented evidence of at least grade 2 arthritis on arthroscopy
4. Patellofemoral pain reproduced with stair climbing, kneeling or squatting but not with standing or walking on level ground
5. A nominated activity that causes worst pain which must be at least moderate in severity (i.e. should be greater than or equal to 4 on a 0 - 10 visual analogue scale [VAS])
6. Pain must have been present with this or other PF activities for the last 3 months
7. The patients will have lateral or medial patellar tenderness on palpation or a positive compression test
8. They should be on a stable medication regimen for 3 months (e.g. if the patients are using non-steroidal anti-inflammatory drugs [NSAIDs] there should be no change)
9. All participants must be willing to wear brace for 3 months daily
10. Potential subjects must have a treatable MRI feature also including either a bone marrow lesion in their PF joint (patella or opposing femoral trochlea) or synovitis on gadolinium scan

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
Planned sample size: 144; UK sample size: 144

### Key exclusion criteria
1. Previous patellar fracture or patellar realignment surgery
2. Predominant symptoms emanating from the tibiofemoral joint or from meniscal or ligament injury or if the patient has rheumatoid arthritis or other forms of inflammatory arthritis
3. If brace is not likely to work because the leg is too large
4. Intra-articular steroid injection into the painful knee in the last month or a viscosupplementation injection (such as Hyalgan, Durolane or Ostenil) with the last 3 months
5. If the patient is planning to move out of the area in next 3 months or will otherwise be unable to attend for follow up assessment
6. Those diagnosed with kidney disease or fatal disease
7. Usual exclusion criteria for the purposes of the MR scan

### Date of first enrolment
17/08/2009

### Date of final enrolment
29/03/2013

## Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**University of Manchester**
Manchester
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# Sponsor information

**Organisation**
University of Manchester (UK)

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**Sponsor type**
University/education

**Website**
http://www.manchester.ac.uk/

**ROR**
https://ror.org/027m9bs27

# Funder(s)

**Funder type**
Charity

**Funder Name**
Arthritis 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
Not provided at time of registration

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/06/2015 | | Yes | No |