

# Stratification of patellofemoral pain (StrOPP)

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| <b>Submission date</b><br>06/02/2017   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>06/02/2017 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>18/12/2017       | <b>Condition category</b><br>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

Patellofemoral pain (PFP) is a common cause of pain in the region of the kneecap that is not related to any other injury or condition. Recent evidence suggests that 1 in 6 adults seeking advice from their GP with knee pain will be diagnosed with PFP. Experts are concerned that PFP may lead to future problems such as knee osteoarthritis (a form of arthritis caused by inflammation, breakdown, and the eventual loss of cartilage in the joints). Treatment failure rates are known to be high in patient with PFP, with a recent study showing that 40% still had a large amount of pain one year following treatment. This has led a group of international experts to say that future research needs to work out sub-groups (groups of people with similar types of knee cap problems) within the PFP population in order to better target treatment to needs of the sub group. Large research trials investigating this sub-grouping approach for PFP are required, however, to ensure the success of such trials, information about whether it would be possible to conduct large scale studies needs to be collected. The aim of this study is to explore the feasibility of targeting treatment to a selected subgroup compared to usual care treatment e.g. standard physiotherapy.

### Who can participate?

Adults between 18-40 who present with kneecap pain

### What does the study involve?

Participants are identified from a larger ongoing study on the basis of having hip muscle weakness at clinical examination. Participants are then randomly allocated into either a matched treatment (MT) group or usual care (UC). Those in the MT group are asked to attend six supervised sessions of physiotherapy aimed at strengthening the hip muscles. Those in the UC group are to continue with the same management of their condition as they were planning to receive before starting the study. At the start of the study and again after 8 weeks participants in both groups completed a range of clinical assessments including strength testing of the knee and hip, movement assesment up and down stairs and questionnaires.

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

Participants may not benefit from participation in the study but it's hoped the information obtained from this study might help to improve the treatment of people with PFP. There are no known risks involved with participating.

Where is the study run from?  
Chapel Allerton Hospital (UK)

When is the study starting and how long is it expected to run for?  
March 2014 to June 2017

Who is funding the study?  
National Institute for Health Research (UK)

Who is the main contact?  
Mr Benjamin Drew  
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## Contact information

**Type(s)**  
Public

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
17453

## Study information

**Scientific Title**  
Stratification of patellofemoral pain using clinical, biomechanical and imaging features

**Acronym**  
StrOPP

**Study objectives**  
Primary aim:  
To explore the feasibility of treatment matched to the specific clinical criteria of a selected subgroup compared to usual care (UC) management.

Secondary aim:

To explore the mechanism of effect of hip strengthening as this has also been recently advocated for trials of physical interventions

### **Ethics approval required**

Old ethics approval format

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

NRES Committee North East- Newcastle & North Tyneside 2, 12/09/2014, ref: 14/NE/1131

### **Study design**

Both; Both; Design type: Process of Care, Cohort study, Not Specified

### **Primary study design**

Interventional

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

Treatment

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

Specialty: Musculoskeletal disorders, Primary sub-specialty: Metabolic Bone Disease

### **Interventions**

Participants are selected from an on-going longitudinal cohort study on the basis of having hip abductor weakness (determined from thresholds defined a priori from age and gender normative data) at clinical examination and randomised into receiving either a matched treatment (MT) or UC in a 1:1 ratio.

MT Group: Participants receive six supervised sessions of physiotherapy once per week. These face-to-face, 1:1 sessions are aimed at targeting coronal, sagittal and transverse hip strength with tailored loading using different resistance theraband. Tailoring the loading is guided by the use of the Rate of Perceive Exertion scale.

UC Group: Participants are advised to continue with the same management of their condition as they were planning to receive prior to the commencement of the study which might include planned physiotherapy, podiatry or no intervention, depending upon participant preference.

Participants in both groups undergo a clinical examination to assess the strength of their knee and hip muscles using an isokinetic dynamometer and movement analysis during stair descent using motion capture at the start of the study and after 8 weeks.

### **Intervention Type**

Other

### **Primary outcome(s)**

1. The conversion to consent (%) is the percentage of those people who are eligible who agree to consent to the trial up to the end of recruitment
2. Eligibility rate (%) is measured as the percentage of people with PFP who are eligible for the study ( e.g.hip weakness) up to the end of recruitment
3. Adherence rate to treatment (%) is measured as the percentage of treatment session completed up to the end of the treatment period (6 weeks)

4. Adherence rate to appointments (%) is measured as the percentage of appointments attended up to the end of the treatment period (6 weeks)
5. Attrition rate (%) is measured as the percentage of participants who remain in the study until the end of follow up at 8 weeks.
6. Missing data (%) is measured as percentage of data missed in the outcome measure at 8 weeks follow up
7. Treatment efficacy is measured using a numerical rating scale, the Anterior Knee Pain Scale (AKPS) and the global rating of change scale (GROC) at 8 weeks follow up

### **Key secondary outcome(s)**

1. Peak hip internal rotation angle (peak IR) of the thigh with respect to the pelvis is measured using VICON motion capture system at baseline and 8 weeks follow up
2. Peak hip adduction angle (peak ADD) of the thigh with respect to the pelvis is measured using VICON motion capture system at baseline and 8 weeks follow up
3. Total coronal hip range of movement (coronal ROM) is measured using VICON motion capture system at baseline and 8 weeks follow up
4. Total transverse hip (ROM) (transverse ROM) is measured using VICON motion capture system at baseline and 8 weeks follow up
5. Peak isokinetic hip abduction strength is measured using Biodex isokinetic dynamometer at baseline and 8 weeks follow up
6. Peak isokinetic knee extension strength is measured using Biodex isokinetic dynamometer at baseline and 8 weeks follow up

### **Completion date**

01/06/2017

## **Eligibility**

### **Key inclusion criteria**

1. Aged 18-40 years
2. Reported insidious (non-traumatic) onset of anterior or retropatellar knee pain
3. Pain on two or more of the following activities: prolonged sitting, kneeling, squatting, running, patella palpation, hopping, stair walking, stepping down or isometric quadriceps contraction
4. Peak hip abduction torque values: Females [18-29 years]  $\leq 94.1\text{nm}$ ; Females [30-39 years]  $\leq 75.8\text{nm}$ ; Males [18-29 years]  $\leq 144.1\text{nm}$ ; Males [30-39 years]  $\leq 139\text{nm}$

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

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Upper age limit**

40 years

**Sex**

All

**Key exclusion criteria**

1. Pain referred from hip or lumbar spine
2. History of previous knee surgery
3. Presence of inflammatory arthritis
4. Other diagnosed knee conditions such as, but not restricted to, meniscal pathologies, quadriceps tendon injuries, patella tendinopathy, tibial tubercle apophysitis; bursitis.
5. Contraindications to MRI which includes: a cardiac pacemaker implanted; pacing wires left in situ after the removal of a cardiac pacemaker; cerebral aneurysm clip in situ; previous intraocular injury involving metal that has not been investigated by an x-ray previously; implantation of an electromechanical device; pregnancy; implantation of a surgical device which is not documented as safe in a 3 Tesla MR scanner

**Date of first enrolment**

24/11/2014

**Date of final enrolment**

01/04/2016

**Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Chapel Allerton Hospital**

Chapeltown Road

Leeds

United Kingdom

LS7 4SA

**Sponsor information**

**Organisation**

University of Leeds

**ROR**

<https://ror.org/024mrx33>

# Funder(s)

## Funder type

Government

## Funder Name

National Institute for Health Research

## Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during the current study will be available upon request from b.drew@leeds.ac.uk

## IPD sharing plan summary

Available on request

## Study outputs

| Output type                          | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>      | results | 04/08/2017   |            | Yes            | No              |
| <a href="#">HRA research summary</a> |         |              | 28/06/2023 | No             | No              |