ISRCTN74560952 https://doi.org/10.1186/ISRCTN74560952

Stratification of patellofemoral pain (StrOPP)

Submission date
06/02/2017

Recruitment status
No longer recruiting

Registration date
06/02/2017

Overall study status
Completed

Last Edited
18/12/2017

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
b.drew@leeds.ac.uk

Contact information

Type(s)
Public

Contact name
Mr Benjamin Drew

Contact details
Leeds Institute of Rheumatic and Musculoskeletal Medicine
University of Leeds
2nd Floor, Chapel Allerton Hospital
Harehills Lane
Leeds
United Kingdom
LS7 4SA
+44 113 3924493
b.drew@leeds.ac.uk

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 prior 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 stystme 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] ≤ 94.1nm; Females [30-39 years] ≤ 75.8nm; Males [18-29 years] ≤ 144.1nm; Males [30-39 years] ≤ 139nm

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/024mrxd33

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?
Results article	results	04/08/2017		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes