

Stratification of patellofemoral pain (StrOPP)

Submission date 06/02/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/02/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 18/12/2017	Condition category Musculoskeletal Diseases	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/03/2014

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

40 Years

Sex

Both

Target number of participants

Planned Sample Size: 77; UK Sample Size: 77

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**

England

United Kingdom

Study participating centre
Chapel Allerton Hospital
Chapeltown Road
Leeds
United Kingdom
LS7 4SA

Sponsor information

Organisation
University of Leeds

Sponsor details

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-
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Sponsor type
University/education

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

Publication and dissemination plan

Planned publication in a high impact peer reviewed journal around one year after the trial end date.

Intention to publish date

01/06/2017

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