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A loaded self-managed exercise programme for patellofemoral pain

Submission date
19/12/2016

Recruitment status
No longer recruiting

Registration date
19/12/2016

Overall study status
Completed

Last Edited
05/07/2019

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Knee pain is a common complaint, with 1 in 6 young adults suffering from pain around the kneecap at any one time. The routine treatment is physiotherapy and painkillers, but current long-term outcomes are poor with 91% of patients reporting pain 4 years after starting treatment. This means that many patients are exposed to potential long-term disability and pain. Patients with this complaint will typically receive a course of physiotherapy which can include a variety of treatments. These may include strengthening exercises, taping, stretches and foot orthoses. The use of strengthening exercises has been shown to be most promising, but the best 'dose' remains unclear. Strengthening exercises which are self-managed and include movements that reproduce the patient's symptoms have been shown to be beneficial for the back and shoulders, but further investigation is needed to evaluate these exercises for the knee and particularly in relation to home based exercise versus usual physiotherapy. The purpose of this study is to evaluate the feasibility of running a large scale study into whether a self-managed weight bearing exercise programme is more effective than usual physiotherapy in reducing pain and improving function in people with pain around the kneecap. As part of this study some people will also be invited to discuss their experience of physiotherapy.

Who can participate?
Adults with knee pain in one or both knees.

What does the study involve?
In the first part of the study, 8-10 people are interviewed in order to find out about the impact that knee pain has on their lives. In the second part of the study, a group of participants are randomly allocated to one of two groups. Those in the first group take part in a loaded self-managed exercise programme for the knee, aimed at addressing lower limb knee and hip weakness. This involves completing exercises prescribed by a physiotherapist designed to strengthen the knee. Participants are advised to push themselves to the point of tiring, maintaining a manageable pain level. Those in the second group receive usual physiotherapy. The length of treatment in both groups is left to their discretion of the treating physician. In both groups, participants have their pain levels and knee function assessed at the start of the

study and then again after three and six months. In the third part of the study, a small group of patients from part two are interviewed in order to find out how acceptable the study procedures have been for them.

What are the possible benefits and risks of participating?
There are no direct benefits involved with participating. There are no disadvantages or risks to taking part in this research. Essentially participants will be receiving a course of physiotherapy as they would expect following a referral to a physiotherapy department. The physiotherapy exercises will likely cause some short term temporary pain and discomfort.

Where is the study run from?
London Road Community Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2016 to March 2019

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

Who is the main contact?
Mr Benjamin Smith
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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
32042

Study information

Scientific Title
A loaded self-managed exercise programme for patellofemoral pain: a mixed methods feasibility study

Study objectives
The aim of this study is to establish the feasibility and acceptability of conducting a definitive randomised controlled trial which will evaluate the clinical and cost-effectiveness of a loaded self-managed exercise programme for people with patellofemoral pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Black Country Research Ethics Committee, 07/11/2016, ref: 16/WM/0414

Study design
Randomised; Both; Design type: Treatment, Education or Self-Management, Complex Intervention, Physical, Rehabilitation, Qualitative

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Musculoskeletal disorders, Primary sub-specialty: Musculoskeletal Pain Disorders; UKCRC code/ Disease: Musculoskeletal/ Other joint disorders

Interventions
Phase 1:
8 to 10 participants will be recruited and undergo individual interviews in order to understand the impact of PFP with their lives. Their physiotherapy will continue as normal.

Phase 2:
Participants are randomised to one of two groups using a web-based randomisation service with secure password protected login using random variable block-size.

Intervention group: Participants participate in the loaded self-managed exercise programme for the knee, aimed at addressing lower limb knee and hip weakness. It is set within a framework of reducing fear/avoidance and with an emphasis on self-management and reducing the need for direct physiotherapy intervention. The exercise will be prescribed by the physiotherapist and will typically involve body weight resistance in the form of a single leg squatting exercise sideways on a step. The patient is advised to exercise to the point of fatigue, through some pain and discomfort, ensuring the pain is manageable. Exercise progression and regression is guided by symptomatic response, such that the patient is advised that on cessation of the exercise the pain should remain no worse than pre-exercise. Patients will be advised to exercise at a level they find acceptable and tolerable. Patients are able to start exercising, if they wish, at a very low level, with little or no short term pain increase, and progress when they feel comfortable and confident.

Control group: Participants receive usual physiotherapy.

Keeping the treatment pragmatic, duration of treatment and frequency of sessions in both treatment arms will be at the discretion of the treating physiotherapist. Participants in both groups are then followed up after 3 and 6 months.

Phase 3:
A sub group of participants (8 to 10) from phase 2, along with a sub-group of the physiotherapists involved in phase 2 (8 –10), will be asked to take part in individual interviews that will explore the acceptability and feasibility of study design parameters and the intervention from phase 2.

Intervention Type
Other

Primary outcome measure
Global rating of change (the proportion of participants who have recovered) is assessed using a 7 point Likert scale ranging from “completely recovered” to “worse than ever” at 3 and 6 months.

Secondary outcome measures
1. Average pain is measured using the visual analogue scale (VAS; 0 to 10 cm) at baseline, 3 and 6 months
2. Kinesiophobia is measured using the Tampa Scale for Kinesiophobia (TSK) at baseline, 3 and 6 months
3. Catastrophizing is measured using the ‘Pain Catastrophizing Scale’ (PCS) at baseline, 3 and 6 months
4. Self-efficacy measured using the General Self Efficacy Scale (GSES) at baseline, 3 and 6 months
5. Leisure time sport or exercises within a week is measured with a questionnaire at baseline, 3 and 6 months
6. Health score ismeasured using the generic Euro-QOL (EQ-5D-5L) at baseline, 3 and 6 months

Overall study start date
01/04/2016

Completion date
31/03/2019

Eligibility

Key inclusion criteria
1. Aged 18 to 40
2. Able to give written informed consent
3. Clinical diagnosis of unilateral or bilateral PFP of greater than 3 months duration
4. Anterior or retropatellar pain reported on at least two of the following activities:
4.1. Prolonged sitting
4.2 Ascending or descending stairs
4.3. Squatting
4.4. Jumping
4.5. Running

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 70; UK Sample Size: 70

Key exclusion criteria
1. Previous knee surgery, or awaiting lower limb surgery
2. Knee ligamentous instability
3. History of patella dislocations
4. True knee locking or giving way
5. Reasons to suspect systemic pathology, or acute illness
6. Pregnancy or breast feeding
7. Patella or iliotibial tract tendinopathy

Date of first enrolment
03/10/2016

Date of final enrolment
01/02/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
London Road Community Hospital
Derby Teaching Hospitals NHS Foundation Trust
London Road
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United Kingdom
DE1 2QY

Sponsor information

Organisation
Derby Teaching Hospitals NHS Foundation Trust

Sponsor details
Royal Derby Hospital
Uttoxeter Road
Derby
England
United Kingdom
DE22 3NE

Sponsor type
Hospital/treatment centre

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 31/03/2020. Also the study will form part of a PhD thesis.

Intention to publish date
31/03/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Benjamin Smith (Benjamin.smith3@nhs.net).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/07/2017		Yes	No
Other publications	qualitative study	23/01/2018		Yes	No
Results article	results	27/03/2019	29/03/2019	Yes	No
Other publications	barriers and facilitators	03/06/2019	05/07/2019	Yes	No
HRA research summary			28/06/2023	No	No