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The effect of stretching and transverse friction massage to gastrocnemius for patellofemoral pain syndrome

Submission date
28/07/2015

Recruitment status
No longer recruiting

Registration date
23/08/2015

Overall study status
Completed

Last Edited
15/10/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Patellofemoral pain syndrome (knee pain in young adults) happens when the kneecap (patella) is affected by imbalances in the muscles surrounding the knee joint. One of the causes is excessive tightness of the calf muscles. This study investigates if a massage technique (called transverse friction massage) combined with a home stretching exercise programme works better in treating the condition than the stretching exercises alone.

Who can participate?
Patients aged 16 or over with patellofemoral pain syndrome.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group A receive a self-stretching programme to do at home. Those in group B hare given the same stretching programme and also the
transverse friction massage to the gastrocnemius (calf muscle). All participants attend the trial participating centre 3 times over the study period. This involves an initial assessment at the start of the study, a follow-up visit 2 weeks into the study and a final one 4 weeks into the study. A review of the participants progress is made at the two follow up visits and those in group B receive their massage treatment during this time.

What are the possible benefits and risks of participating?
The use of stretches and transverse friction massage to the calf muscles are treatment techniques that are commonly used by physiotherapists for this and other conditions. The risk to the patient is minimal. On rare occasions there may be some mild soreness to the calf muscle however this usually settles within a 24 hour period.

Where is the study run from?
Northern Devon District Hospital and Precision Physiotherapy, Bideford (UK)

When is the study starting and how long is it expected to run for?
October 2014 to September 2015

Who is funding the study?
Middlesex University (UK)

Who is the main contact?
Mr Stuart Hall

Contact information

Type(s)
Public

Contact name
Mr Stuart Hall

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of stretches and transverse friction massage to the gastrocnemius in patients with patellofemoral pain syndrome (PFPS) – a pilot interventional study

Study objectives
1. Hypothesis 1
There is a reduction in pain with patients with PFPS who receive transverse friction massage and stretches compared to patients who receive a stretching regimen alone
2. Hypothesis 2
There is an improvement in function with patients with PFPS who receive transverse friction massage compared to patients who receive a stretching regimen alone
3. Null hypothesis 1

There is no difference in pain with patients with PFPS who receive transverse friction massage and stretches compared to patients who receive a stretching regime alone
4. Null hypothesis 2
There is no difference in function with patients with PFPS who receive transverse friction massage and stretches compared to patients who receive a stretching regime alone

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. London Sport Institute Ethics Sub-Committee, 21/04/2015, ref: 351
2. West of Scotland Research Ethics Service, 10/09/2015, ref: 15/WS/0172

Study design
Pilot interventional study

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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Patellofemoral pain syndrome

Interventions
There will be two treatment arms for the study which will be called groups A and B.
Group A will be taught home stretches for their gastrocnemius.
Group B will be taught the same stretching programme however will also recieve 3 sessions of transverse friction massage which will be applied to the lateral head of gastrocnemius for 10 minutes.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain measured on VAS and Eccentric step down test at baseline, 2 weeks and 4 weeks follow-up

Secondary outcome measures
Function measured by Modified Functional Index Questionnaire and Eccentric step down test at baseline, 2 weeks and 4 weeks follow-up

Overall study start date
10/10/2014

Completion date
28/09/2015

Eligibility

Key inclusion criteria
Participants may be aged from 16 and above, with no upper age limitation. History of characteristic history and symptoms of patellofemoral joint pain for more than 6 weeks, defined as retropatellar pain during physical activities such as jumping, running, squatting and going up and down stairs.
Exhibit at least two of the following physical criteria:
1. Pain on direct compression of the patella against the femoral condyles with the knee in full extension
2. Tenderness of the posterior surface of the patella on palpation
3. Pain on resisted knee extension in 15° of flexion
4. Negative findings in the examination of the other knee structures, i.e. ligaments, menisci, bursae, synovial plicae, Hoffa's fat pad, Iliotibial band, and the hamstrings, quadriceps, patellar tendons and their insertions.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Referred pain to the lower limb from any spinal, pelvic or hip joints
2. Pregnancy
3. Joint replacement, ligamentous or meniscal surgery
4. Intra-articular loose bodies
5. Increased temperature of the knee joint
6. Abnormal illness behaviour
7. Rheumatoid arthritis
8. Heart conditions
9. Peripheral vascular disease

Date of first enrolment
01/06/2015

Date of final enrolment

28/09/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northern Devon District Hospital
Raleigh Park
Barnstaple
United Kingdom
EX31 4JB

Study participating centre
Precision Physiotherapy
52 Bay View Road
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Bideford
United Kingdom
EX39 1BH

Sponsor information

Organisation
Middlesex University

Sponsor details
c/o Dr Elaine Atkins
Programme Leader MSc Orthopaedic Medicine
The Archway Campus
Highgate Hill
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N19 5LW

Sponsor type
University/education

Website

http://www.mdx.ac.uk/

ROR
https://ror.org/01rv4p989

Funder(s)

Funder type
University/education

Funder Name
Middlesex University

Alternative Name(s)
Middlesex University, London, Middlesex University London, MDX

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No