Effiectiveness of manual therapy compared with physical therapy for patients with patellofemoral pain syndrome: a randomized controlled trial

Published: 20-09-2016
Last updated: 16-04-2024

The purpose of this study is to evaluate the effect on the outcome measures function, pain, and strength of manual therapy of the lumbar vertebral spine, the SIG and hip joint in patients with the PFPS comparing with the effect of physical therapy…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON43253

Source
ToetsingOnline

Brief title
manual therapy bij patients with patellofemoral pain syndrome

Condition

- Joint disorders

Synonym
Anterior knee pain & retropatellar chondropathy.

Research involving
Human

Sponsors and support

Primary sponsor: Tamminga groep

Source(s) of monetary or material Support: Er is vanuit de VUB 1000 euro beschikbaar gesteld om de aanvraag te bekostigen.

Intervention

Keyword: anterior knee pain, manual therapy, patellofemoral pain syndrom, physical therapy

Outcome measures

Primary outcome

The AKPS questionnaire is used as the primary outcome measure The AKPS is a questionnaire with 13 items that together give a maximum of 100 points which lower scores indicates an increasing degree of limitations. (Kujala 1993) The AKPS has high test-retest reliability and good internal consistency (ICC = 0.95) (Horton 2005) The Dutch translation used in this study is similar to the original English questionnaire. The standard error of measurement (SEM) here is 0.78 and the smallest detectable change is (SDC) ± 11.01. (Ummels 2015) This is a scale from 0 mm (no pain) to 100 mm (worst possible pain).

Secondary outcome

As secondary outcomes, the VAS and Biodex are used. The VAS has a good internal consistency, test-retest reliability and responsiveness (Lara Muñoz 2005) The VAS has a minimal Important Change (MIC) of 30% or 20 mm from the starting value. (Ostelo 2008). The VAS questionnaire is used to identify the minimum, maximum and average pain. VAS for average and maximum pain and AKPS are the most reliable and responsive outcome measures in the treatment of PFPS. The AKPS has a moderate correlation with the VAS (r = 0.74) (Crossley 2004). So, it does not always have to give an improvement in function when there is an improvement of the pain.

The Biodex has an acceptable reliability and validity (Drouin 2001 Valovich 2001) It gives reliable results for torque, position and angular velocity on repeat testing on the same day and on different days. The validity of the isometric torque and position measurements is acceptable for clinical and research purposes (Drouin 2003).

Study description

Background summary

The Patellofemoral Pain Syndrome (PFPS) is a condition characterized by retropatellar and / or peripatellar pain. Pain occurs on or after activities in which the knee is loaded (walking, running, jumping, climbing stairs, squats and prolonged sitting. (Davis et al. 2010, Cook et al. 2010). the PFPS is one of the most frequent knee injuries. Approximately 25% of all knee injuries is diagnosed as the PFPS. (Fredericson et al. 2006)
The incidence of PFPS was 22/1000 person-years. Women are twice as likely to develop the PFPS (Boling et al. 2010). Due to the large impact of the PFPS on the daily function, the risk of knee osteoarthritis in later life (Thorstensson 2004, 2008) and its high prevalence, an effective treatment strategy is important. The studies on the treatment of PFPS are numerous. However, there is still no clear consensus on how to treat this condition.
For example, insoles regularly prescribed, but with varying results (Barton 2010). Also, therapy aimed at enhancing the strength of the quadriceps, gluteaal- and calf muscles, whether or not combined with mobilization of the patellofemoral joint, has shown to reduce pain and improve motor control (Fucuda 2010 Kooiker 2014, Peters et al. 2013). However, this does not always work well for each patient. The orthopedic surgeons of the Bergman Clinic regularly sends patients to the authors to further chart the symptoms and for treatment. These patients often already had one or more sections with or without evidence-based targeted physiotherapy with moderate to completely no effect. From clinical experience of the authors in a pilot of 45 patients with PFPS and a case series of 14 patients (Nieuwenhuizen 2013) has shown that there is a causal relationship between the PFPS and disorders in the thoracolumbar spine and the hip joint. These disorders were found in the mobility of the thoracolumbar junction (TLO) and / or connective tissue of the lumbar spine (lumbar spine), the sacroiliac joint (SIG) and hip extension. Treatment through manual therapy for these disorders gave a significant improvement in function and pain of the knee
The positive experiences from the pilotstudy concerning the treatment of these

disorders, the researchers decide to use this as an intervention in this study. Our hypothesis is that manual therapy will give better results in the treatment of the patellofemoral pain syndrom than conventional treatment in terms of pain, function, and strength.

Study objective

The purpose of this study is to evaluate the effect on the outcome measures function, pain, and strength of manual therapy of the lumbar vertebral spine, the SIG and hip joint in patients with the PFPS comparing with the effect of physical therapy on these outcome measures with training the strength of the hip and gluteal muscles in these patients.

Study design

The study is a randomized controlled trial with two intervention groups.

Intervention

One group gets the intervention with manual therapy and the other group receives the intervention physiotherapy. After intake follows a treatment-free period of 3 weeks. At the start of the treatment intervention pain, function and strength will be measured as a baseline measurement. The intervention manual therapy consists of 6 sessions of manual therapy with a frequency of once a week focused on the disorders found in the lumbar spine, hip and SIG. The physiotherapy intervention consists of strengthening the gluteal and surrounding muscles of the knee such as the quadriceps and calf muscles coupled with mobilization of patellofemoral joint with a frequency of once a week for the duration of 6 weeks.

Study burden and risks

The load for the subjects is as follows:
- One time to physiotherapy department to subscribe for research participation directly from the orthopedic surgeon
- subscribe online for taking surveys. These questionnaires are 4x times conducted over a period of 15 weeks. This load equals the load of questionnaires to patients in regular care. In addition, the VAS (min, max, average) is conducted digitally once a week in the first three weeks.
- 3 times a test on the Biodex. This is a (maximum) strength test and lasts about 10 minutes plus 15 minutes warming up.
- 6 times treatment physiotherapy or manual therapy in the clinic. The risk of physical therapy treatment is negligible. There is no known evidence to the authors that this treatment can cause harm. About the treatment manual therapy can be said that the risk is very low. This is a frequently performed treatment in the standard care. The literature indicates that the risk of manipulations

in the lumbar spine is very low. About the treatment physiotherapy and manual therapy can be said that this is done with the knowledge of the most recent evidence. Conducting the survey is justified because of the low risk and the expected significant improvement of both therapies.

Contacts

Public
Tamminga groep

Jan cornelisz maylaan 6
utrecht 3526 GV
NL
Scientific
Tamminga groep

Jan cornelisz maylaan 6
utrecht 3526 GV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The clinical diagnosis of PFPS was formed if the subject had a self complaint of atraumatic uni- or bilateral anterior knee pain that was aggravated with at least two of the following activities: a positive patella compression test, squatting, prolonged sitting, and ascending of descending the stairs.

Exclusion criteria

Exclusion criteria included pain less than 3 months, prior knee or spine surgery, severe lumbosacral nerve root compression signs. Other exclusion criteria included clinical signs of ligamentous instability or suspected meniscal injury, patellar tendinopathy, (sub)luxations of the patella, pregnancy, osteoporosis, neurologic disorders. MRI, xray and/ or echo will be used for exclusion.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-12-2016
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	20-09-2016
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL57207.096.16