ELSEVIER

Physiotherapy 99 (2013) 126–131

Physiotherapy

Dose–response effects of medical exercise therapy in patients with patellofemoral pain syndrome: a randomised controlled clinical trial

Berit Østerås [a,*], Håvard Østerås [a], Tom Arild Torstensen [b], Ottar Vasseljen [c]

[a] *Department of Physiotherapy, Faculty of Health Education and Social Work, Sør-Trøndelag University College, Trondheim, Norway*
[b] *Holten Institute, Lidingö, Sweden*
[c] *Department of Public Health and General Practice, Faculty of Medicine, Norwegian University of Science and Technology, Trondheim, Norway*

Abstract

Objectives To evaluate two different therapeutic exercise regimens in patients with patellofemoral pain syndrome (PFPS).
Design Multicentre, randomised controlled clinical trial.
Setting Three primary healthcare physiotherapy clinics.
Participants Forty-two patients with PFPS were assigned at random to an experimental group or a control group. Forty participants completed the study.
Interventions Both groups received three treatments per week for 12 weeks. The experimental group received high-dose, high-repetition medical exercise therapy, and the control group received low-dose, low-repetition exercise therapy. The groups differed in terms of number of exercises, number of repetitions and sets, and time spent performing aerobic/global exercises.
Main outcome measures Outcome parameters were pain (measured using a visual analogue scale) and function [measured using the step-down test and the modified Functional Index Questionnaire (FIQ)].
Results At baseline, there were no differences between the groups. After the interventions, there were statistically significant ($P < 0.05$) and clinically important differences between the groups for all outcome parameters, all in favour of the experimental group: −1.6 for mean pain [95% confidence interval (CI) −2.4 to −0.8], 6.5 for step-down test (95% CI 3.8 to 9.2) and 3.1 for FIQ (95% CI 1.2 to 5.0).
Conclusion The results indicate that exercise therapy has a dose–response effect on pain and functional outcomes in patients with PFPS. This indicates that high-dose, high-repetition medical exercise therapy is more efficacious than low-dose, low-repetition exercise therapy for this patient group.
Registered on http://www.clinicaltrials.gov (identifier: NCT01290705).

Keywords: Patellofemoral pain syndrome; Exercise; Dose–response; Pain; Function

Introduction

Patellofemoral pain is characterised by anterior or retropatellar pain associated with activities that load the patellofemoral joint, such as ascending or descending stairs, squatting, running and kneeling. Patellofemoral pain syndrome (PFPS) is the most common complaint affecting the knee [1]. In sports medicine practices, PFPS is reported to represent up to 25% of all new running injuries [2]. Women are more likely to be affected than men [3].

The main symptom of PFPS is pain, and the condition generally progresses to impaired function. Based on underlying theoretical constructs and previous research, several factors or impairments such as muscle weakness [4], soft tissue tightness [5], structural and biomechanical alterations of the lower extremities [6], quality of movement [7] and psychological factors [8,9] have been suggested to contribute to the occurrence of PFPS. There is no agreement on the aetiology of PFPS or the most appropriate treatment, but there is general consensus that the preferred treatment approach is non-surgical [10].

* Corresponding author at: Department of Physiotherapy, Faculty of Health Education and Social Work, Sør-Trøndelag University College, Ranheimsveien 10, 7004 Trondheim, Norway. Tel.: +47 73 55 92 76; fax: +47 73 55 92 79.
E-mail address: berit.osteras@hist.no (B. Østerås).

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http://dx.doi.org/10.1016/j.physio.2012.05.009

For many years, the non-surgical treatment approach has been to address the assumed abnormal tracking and/or malalignment in patients with PFPS [1], and this method typically includes quadriceps strengthening [2,11,12], patellar bracing and taping [13,14], soft tissue mobilisation and stretching [15]. Unfortunately, the results of such treatment approaches have been mixed [2,13]. A review of exercise therapy for PFPS concluded that there is limited evidence for the efficacy of exercise in treating pain, and conflicting evidence for functional outcome [16]. It is reported that approximately 25% of patients continue to have pain and dysfunction 1 year or more after physiotherapy, but physiotherapy is still the most commonly used conservative treatment for PFPS [8].

The effects of different treatment doses using exercise therapy in patients with PFPS have not been examined. Studies in patients with longstanding subacromial pain have reported a dose–response effect of exercise therapy, with high-dose, high-repetition medical exercise therapy (MET) found to be the most efficient approach [17,18]. The mechanisms behind the clinical effects are still unclear, although tendon regeneration has been demonstrated [19], possibly due to increased circulation and intermittent tension release mechanisms [20]. Perceived pain reduction and improvements in function are also thought to pursue central pain modulation induced by considerable amounts of aerobic exercise [21].

The purpose of this trial was to study the dose–response effects of graded exercise therapy on pain and functional outcomes in patients with PFPS, comparing two different therapeutic exercise regimens.

Methods

Study design

This was a multicentre, randomised controlled clinical trial. The study protocol was approved by the Regional Ethics Committee, and is registered on http://www.clinicaltrials.gov (identifier: NCT01290705). Eligible patients were given written information about the study before giving their written consent to participate.

Patient selection

Participants were recruited by general practitioners and orthopaedists referring patients with PFPS to the three physiotherapy clinics involved in this study. The inclusion criteria were: (1) anterior or retropatellar pain from at least two of the following activities – prolonged sitting, climbing stairs, squatting, running, kneeling and hopping/jumping; (2) insidious onset of symptoms unrelated to a traumatic incident; and (3) presence of pain on palpation of the patellar facets or positive physical tests on grinding of the patella, Clarke's test or patellar crepitus. Eligible patients had to be aged 16 to 50 years, with untreated PFPS and symptoms lasting for more than 2 months. The age range was chosen to avoid difficulties in differentiating between PFPS, late symptoms of apophysitis (Osgood–Schlatter's disease) and early symptoms of osteoarthritis. The exclusion criteria were knee osteoarthrosis/arthritis, previous knee injury or knee surgery, patellar tendinopathy, Osgood–Schlatter's disease or other defined pathological conditions of the knee. The selection criteria are similar to those used in previous studies on PFPS [2,14,22,23].

Randomisation

Following informed consent and baseline assessment, patients were allocated at random to an experimental group or a control group using block randomisation. The blocks (of 4 to 10, with concealed envelopes with block-specific numbers) were distributed to the clinics and completed one at a time to ensure even distribution between the groups. Each participant drew an envelope with a block-specific randomised number corresponding to a group number on a list prepared by the main investigator. Randomisation was not stratified by centre because of the calculated small sample size. Allocation was concealed for the participants and physiotherapists until the first treatment.

Sample size

Sample size was calculated using a predetermined difference between treatment groups of 20% change in pain on a 10-cm visual analogue scale. This effect is considered to be better than a minimal clinically important difference based on the results of previous comparative studies in PFPS [14,15,24]. Sample size calculation with a standard deviation of 2 cm showed that 17 participants were required in each group to have 80% power to significantly detect a 20% difference at the 5% level. This number was increased to 21 per group to allow for possible withdrawals.

Interventions

MET is a concept in physiotherapy where the exercises are constructed according to different positions (both open and closed chain), with variable loads and ranges of motion to enable the patients to perform highly repetitive ($\geq$30 repetitions) exercises without increasing pain [17,18]. The experimental group in this study received high-dose, high-repetition exercises according to MET principles, while the control group received low-dose, low-repetition exercises. The term 'high-dose, high-repetition' refers to a higher number of exercises, higher number of repetitions and sets, and a considerable amount of aerobic/global exercises using a stationary bike. The exercises in the control group programme were termed 'low-dose, low-repetition', referring to the lower number of exercises, lower number of repetitions and sets, and the brief sequences of aerobic/global exercises. Dosage parameters in the control group were graded in accordance