Author's response to reviews

Title: Knee arthroscopy and exercise versus exercise only for chronic patellofemoral pain syndrome. A randomized controlled trial.

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Author's response to reviews: see over
Reviewer's report
Title: Knee arthroscopy and exercise versus exercise only for chronic patellofemoral pain syndrome. A randomized controlled trial.
Version: 2 Date: 6 September 2007
Reviewer: Ewa M Roos
Reviewer's report:
General
I find that the text has improved in clarity and figure and tables are much easier to follow. The additions of the exercise program and the outcome score are most helpful. I do however have some comments on aspects which I think can be further improved.

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Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

P3, P2, L7. Surgical interventions…. It is not logical that you 1) in the intro state that surgical interventions should be based on diagnostic findings 2) in the methods state that patients with meniscal symptoms were excluded 3) have performed meniscectomy in included subjects. I am well aware of the clinical reality and reasoning behind this and it might make sense for an orthopedic surgeon, but it does not make sense in a scientific trial and to a scientist. You have improved the understanding by separately giving data for these patients in the results section but still, I suggest you discuss why you did perform meniscectomies in subjects without symptoms thereof.

Authors response:
We would kindly remind the reviewer of the fact that some patients with tibio-femoral joint problems (osteochondritis, partial meniscal tears etc.) report mainly anterior knee symptoms. Also, there may be some fluctuation in the location of the symptoms related to some specific pathology. As the selection of subjects and clinical treatment followed the commonly recommended treatment methods, the option of leaving untreated subjects with knee symptoms plus a finding of meniscus pathology would have attracted a great deal of criticism. This is the logic behind our approach. We want to point out that we tried to avoid this type of problem as far as possible in our design as we included a second clinical examination, which was performed by an experienced orthopaedist at the ORTON Orthopaedic Hospital.
Arthroscopy showed two patients to have meniscal pathology; however, they both reported anterior knee pain symptoms at the baseline examination. Thus, these patients fulfilled our inclusion criteria and were included in the study. However, we could not be sure whether these symptoms were due to meniscus pathology. These patients were treated according to our preliminary pre-determined guidelines, which followed generally accepted recommendations. We have discussed the treatment of the patients with meniscal lesion.

P5, P3, L2. I find it hard to believe that the study coordinator did not have any expectations concerning the results. This statement needs to be modified!

Authors response: The background for not blinding the outcome assessor was that the two last authors asked the first author before the study whether he had any presuppositions as to whether arthroscopy would help in this protocol. As the first author had no presuppositions on this issue, we decided not to do exhaustive blinding procedures concerning this data collection. We do not believe that this decision introduced any bias into our study design. We have modified the text: … the study coordinator had no presuppositions as to which of the groups would show better results…

The Kujala score. Thank you for providing the Kujala score. This score seems to be developed to reflect the surgeon’s perspective of what is important to patients with PFPS (which is fine, but distinctly different from instruments developed to reflect the patient’s opinion). However, my guess is also that the score was developed to be observer administered (as opposed to patient administered). One example is items 11-13 (patellar movement, atrophy and flexion deficiency) which are not easy concepts for patients. You state that the Kujala score reflects knee function. This statement has to be modified since the included items reflect outcomes on all ICF levels including some of doubtful relevance to patient’s perception of knee function.

Authors response: The score was not developed as observer administered. It is possible that in some cases a physiotherapist or a physician making objective measurements would score some items (such as patellar movement, atrophy and flexion deficiency) differently. We believe that when a patient responds to these items it is likely that more severe changes (often affecting function) will be documented. When developed the score in about...
1991 ICF levels were not discussed and the focus was largely on recording pain, as we are dealing with a pain syndrome. It is a somewhat problematic relating pain to ICF levels. The items are related to body function and activity, and in some instances body structures. However, the main focus is on pain related to function and activities. Crossley et al (2004) describes the scale in the validity paragraph: "AKPS incorporates questions about function and disability with pain."

Furthermore, Crossley et al. (2004) analyzed different outcome measures in patients with PFPS, and they found that the mean change (final minus baseline assessment scores) in the Kujala score correlated moderately (.69, P<0.001) with participant-perceived global rating of change. (Crossley KM, Bennell KL, Cowan SM, Green S: Analysis of outcome measures for persons with patellofemoral pain: which are reliable and valid? Arch Phys Med Rehabil 2004, 85:815-822). We wanted to use the score in the same form as it has been used in more than 60 other studies (see ISI Web of Knowledge citations to the original score) to facilitate comparison with other studies on patellofemoral problems and as others have validated it. We have slightly modified the description of the score given in the text.

Crossley consider an improvement of 2 points on the Kujala score as clinically significant. In your data analysis section you calculate your sample size based on a 10-point difference in improvement between groups. If I have understood correctly, this means that you do not have power to study what is considered to be the clinically minimal important difference for the Kujala score? In comparison with other similar outcome measures 2 points seem to be a very small difference. This has to be sorted out.

Authors response: We mentioned in the methods section that according to Crossley et al. (2004) a clinically significant improvement is deemed to have occurred when the patient’s Kujala score shows an increase of from eight to ten points. We used a 10-point difference in calculating our sample size so as to be able to detect clinically meaningful difference between the groups. (Crossley KM, Bennell KL, Cowan SM, Green S: Analysis of outcome measures for persons with patellofemoral pain: which are reliable and valid? Arch Phys Med Rehabil 2004, 85:815-822).
P8, P3. Unless you have a scientific reason to determine the cut-off for moderate improvement this whole paragraph should be deleted. If you have a scientific reason, please describe and give reference.

This is a validity item that is rather often requested in this type of research. Outcome scores should correlate logically with simple questions on improvement. We have left this paragraph in the text, but it is OK if it is deleted as it does not in any way change the message of our paper. It has been shown elsewhere what constitutes a clinically significant improvement. We would prefer these data are also shown in the present material.

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

P4, P2, L3. Delete “conservatively”.

Authors response: We agree with the reviewer and we have deleted the word.

P4, P3, L4. The approximate duration of each visit was 30 minutes. How long time did the exercise program take? Please add this info. Regarding the compliance I guess that it was a dichotomous answer, yes/no on a daily basis, not indicating the time spent exercising? Without this info and without objective measures of muscle strength it is difficult to estimate the real compliance with exercise.

Authors response: We agree with the reviewer and we have added the duration of the daily home exercise session. We have also more clearly described the way we estimated weekly home exercise compliance. All our patients had knee pain at the baseline, and thus we did not think it useful to measure muscle “strength” in such patients.

P5, P2, last line. The one patient that had a delayed start of the exercise program, did she still exercise for the same amount of time or did she stop at the same week after arthroscopy as the other? For how many weeks was the start delayed?
Authors response: Her exercise program was delayed for one week; she started exercising four weeks after arthroscopy, and she exercised for eight weeks.

P7, P4, L1. Substitute “during” with “after the exercise intervention and prior to the 9 month follow up” to more correctly reflect the info given in the figure.

Authors response: We agree with the reviewer, and we have modified the sentence.

Figure 1. The person with delayed start of exercise in the arthroscopy group seems to have started at three weeks (n=27)? If this person started exercising later than at three weeks, it should be given in figure when this person started.

Authors response: We agree with the reviewer, and we have included the information.

Table 2. Please check your unit for BMI (kg/cm2).

Authors response: We have corrected the unit.

Table 4. Please omit percentages for number of arthroscopy findings. Give numbers only.

Authors response: We agree with the reviewer, and we have removed percentages.

Discretionary Revisions (which the author can choose to ignore)
Which journal?: Appropriate or potentially appropriate for BMC Medicine: an article of outstanding merit and interest in its field
What next?: Accept for publication in BMC Medicine after minor essential revisions
Quality of written English: Needs some language corrections before being Published
Statistical review: No
Declaration of competing interests: ‘I declare that I have no competing interests’