Author's response to reviews

Title: Six-week high-intensity exercise program for middle-aged patients with knee osteoarthritis - a prospective, randomized, and controlled study

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Author's response to reviews: see over
Comments to the reviewer

Attached you find the revised manuscript entitled ”Six weeks…..”. We thank you for your comments. We have considered all suggestions and made changes accordingly as outlined below. Below you find our replies (in yellow) to you comments inserted directly after each of your comments.

Reviewer's report
Title: Six-week high-intensity exercise program for middle-aged patients with knee osteoarthritis - a prospective, randomized, and controlled study
Version:3 Date:11 March 2005
Reviewer: Marlene Fransen

Reviewer's report:
General

Throughout the manuscript you need to eliminate all within group results. They are misleading. You need to compare to the control group at all times, and not simply conclude a positive results when the intervention group demonstrated a significant improvement and the control group did not. This is not a valid analysis for a RCT. You need to compare statistically either the outcome scores at 6 weeks or 6 months (independent comparison) or the change scores (paired comparison). The latter is often more appropriate with small sample sizes and when you are not adjusting for baseline differences. When you do this you will probably find (looking at the 95% CIs) that there are no significant differences between the groups in any of the outcome measures.

All within group results are eliminated, and only comparisons to the control group are shown. The change scores (95 % CI) are compared throughout the manuscript.

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

Abstract: Do not understand 'measures of aerobic capacity and functional performance were used to ensure the effectiveness of the intervention'. What is the explanation that there were no differences. Drop all within group results – they are very misleading. For example, while aerobic capacity improved in the exercise group, it also equally improved in the control group!!

Randomised numbers belong in methods, not results

‘Measures of aerobic capacity …’ is deleted, and within group comparisons are changed to be comparisons to the control group. Randomized numbers are stated in methods

Background: Needs rewriting – poor English language. 2nd last sentence not justified.

Background is rewritten. 2nd last sentence is deleted

Methods: Drop outline of exercise intervention details (1-6). This information is provided in the appendix.

Again, the section the physical outcome measures to ‘ensure the effectiveness of the intervention’ is not correct. The main outcome was KOOS. The exercise program may or may not result in changes in these physical measures. The assumption that if patients exercised sufficiently, these physical measures would improve is very tenuous. Depends
on too many other factors and is not a simple linear association. Better just to include these measures as secondary outcome measures, rather than ‘tests of compliance’.

Methods: intervention details are deleted. Tests of physical performance are presented as secondary outcome measures.

Statistics: Need to use tests to ‘compare’ changes rather than ‘study’ changes.

Statistics: ‘study changes’ is replaced with ‘compare changes’

Results:
Limit analysis (and p-values) to two group comparisons (either independent or paired). Drop the with-in (one) group differences. This analysis should, in fact, be comparing within group differences between the two groups not just assessing changes within one group.

Results: Paired group comparisons of within group differences are reported.

Add some text about Table 4

Table 4 is presented as an additional file.

Discussion: Will probably need revision when eliminating the ‘within (one) group’ results.

Discussion: revised according to the revision of the results section. For example, main message is changed to: Six weeks of intensive exercise had no effect on pain or self-reported function in middle-aged patients with symptomatic and moderate-severe radiographic knee osteoarthritis. And further, paragraph including the improvement in functional performance is deleted.

Tables: need revision in light of above. P values should be limited to differences between groups, not within one group.

Tables 2-3: Revised. P-values show between group comparisons. Table 4 is presented as an additional file.

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Needs some language corrections before being published

Language has been revised

Statistical review: No

Declaration of competing interests:
I declare that I have no competing interests