Author's response to reviews

Title: Effects of self-management, education and specific exercises, delivered by health professionals, in patients with osteoarthritis of the knee.

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Author's response to reviews: see over
Monday, September 8, 2008

Dear Sir/Madam,

Following the revision of manuscript:
**MS: 7462001912123334**  Effects of self-management, education and specific exercises, delivered by health professionals, in patients with osteoarthritis of the knee.

I have included responses (in red font) to the reviewer. I apologise for the delay in my response and appreciate your patience.

Best wishes,

Sophie Coleman RN BSc N
Reviewer's report

Title: Effects of self-management, education and specific exercises, delivered by health professionals, in patients with osteoarthritis of the knee.

Version: 1 Date: 11 August 2008

Reviewer: Graeme Jones

Reviewer's report:

The rational for this protocol is well developed and stated. My comments mainly relate to the small print areas

1. The diagnosis of OA needs to be firmer. Physician diagnosis is not enough. Does there have to be clinical evidence, pain or Xray change to make this diagnosis? I would prefer the ACR clinical criteria with at least some radiographic evidence. There needs to be standardisation of Xray scoring.

Patients fulfil clinical criteria for OA knee and must have X-Ray diagnosis but no attempt will be made to grade severity as it is not feasible within the constraints of the OAK study. X-Ray evidence will be used in this study to ensure a definitive diagnosis of OA but not used to rate OA severity. It will be used in combination to confirm the clinical diagnosis of OA made by the GP/Specialist. ACR criterion is most sensitive in identifying moderate to severe OA but is not as sensitive in identifying mild OA (who are included in this study). To ensure that participants are able to complete the program in its entirety entry criteria requires that no surgery is planned within 6months of commencement of the program.

2. What do the authors plan to do with severe knee OA? they will exclude those with planned TKR but what about bone on bone change?

The OAK program is offered to all people with all OA regardless of severity. The holistic approach of the program includes healthy life style instruction, education, and behavioural changes under the constructs of self-management. Since group and individual support is offered as part of the program disease severity is not considered to be used as criteria to exclude people from attending.

3. The authors correctly point out that the WOMAC is sensitive to change but this is only true if scores are high enough to begin with eg a person with a pain VAS of 10/100 has limited scope for improvement. Will the authors predefine a pain level for entry as is standard for many OA trials?

Pain is not listed as entry criteria. There are also healthy lifestyle messages within the program and those with mild OA may potentially benefit from changes in behaviour that encourage exercise and healthy life-style changes.

4. The assessment period on controls does not match that in the intervention group. They will receive the SMP from week 8 but wont be assessed until 6 months. How will this be dealt with in the analysis especially when the intervention group receive no intervention in this period?

The control group and the intervention group have assessments at the same time-points throughout the study: BL, Week8, and 6months (see flowchart).
5. sample size calculations are given for one primary outcome. Please provide the full data for the main primary outcome (the WOMAC) and an estimate of power for the secondary outcomes.

A priori power calculations for this study were based on the quality of life outcome as measured by the SF36. The SF-36 was chosen as it is the least sensitive and requires greater power to detect changes in treatment differences with respect to pain and physical functioning in people with OA. Sample size has been calculated according to guidelines in the SF36 Users Manual, to determine differences in changes over time between the intervention and control groups using a repeated measures design allowing an inter temporal correlation between scores of 0.60. A pilot study (of the OAK program) SF36 data showed an average difference of 10 points across the eight domains measured. Assuming this level of improvement is achieved in the intervention group and there is no change in the control group and allowing for a 10% drop out rate, the number of participants required per group would be 60. In the pilot study, we had a drop out rate of 5% over 3 years, so allowing 10% is a conservative estimate. Differences in changes in functional ability measured using the WOMAC, similar in magnitude to those previously documented would also be detectable in a sample of this size.

We did not determine sample size using secondary outcomes. However the FKAT was validated against the WOMAC and there was found to be a significant correlation with stiffness (R=0.475), function (R=0.459) and to a lesser extent pain (R=0.376), which is not surprising since the WOMAC function dimension mimics the FKAT (as a functional task) more than pain.

**Level of interest:** An article whose findings are important to those with closely related research interests  
**Quality of written English:** Acceptable  
**Statistical review:** No, the manuscript does not need to be seen by a statistician.  
**Declaration of competing interests:**  
'I declare that I have no competing interests'