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.

Authors:

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Version: 3 Date: 30 September 2008

Author's response to reviews: see over
Dear Sir,

Regarding manuscript: 7462001912123334

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

S. Coleman, N.K. Briffa, G. Carroll, C. Inderjeeth, N. Cook, J. McQuade

I have submitted a revised manuscript with the formatting revisions as requested.

The table has been moved to text following the references. The table title is above the table.

Table shading has been removed.

Figure legends have been moved to a position after the references.

Figure cropping has been done as closely as possible to minimise white space around the image.

The manuscript has been checked for any typographical errors.

Thank you for considering our manuscript for publication.

Please contact me if you require further information.

Kind regards,

Sophie Coleman
ARTHRITIS FOUNDATION OF WA
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Editor’s comments:

1. You should include within the manuscript a flow chart of the progression of participants through the trial, from sampling, through recruitment, to drop-out or the end of the study. This was included as an attachment labelled “Figure 1 Flow Chart”. This has been reformatted to fit onto one page.

2. You should include a statement within the text of the manuscript of whether consideration was given to sample size.

This program meets the Australian criteria for a quality assurance program (http://www.nhmrc.gov.au/publications/synopses/e46syn.htm) and therefore a priori sample size calc not calculated. Enrollment was discontinued after 8 groups were recruited. An abstract had been submitted to the ACR scientific meeting and this supported the decision to discontinue recruiting to analyse the data.

3. We require that you send to us statements of ethical approval from the two bodies that gave approval, along with information on the make-up of those boards. Please send this by email, fax or post. Note that the second board does not appear to us to be a formal HREC as it is made up of the authors
and three others. Please include the reference number of the ethics boards within the manuscript.

This Quality Assurance program meets the Australian criteria for QA (http://www.nhmrc.gov.au/publications/synopses/e46syn.htm) as described in the following excerpt from the publication:

AHEC therefore advises that an appropriately planned activity can proceed without review by an HREC if:

**Both**

(a) the activity is undertaken with the consent of the patients, carers, health care providers or institutions involved;

or

is consistent with National Privacy Principle 2.1(a), which states:

‘An organisation must not use or disclose personal information about an individual for a purpose (the secondary purpose) other than the primary purpose of collection unless’ … ‘both of the following apply:

(i) the secondary purpose is related to the primary purpose of collection and, if the personal information is sensitive information, directly related to the primary purpose of collection;

(ii) the individual would reasonably expect the organisation to use or disclose the information for the secondary purpose’;

and

(b) it is an activity where participants, including patients, carers, health care providers or institutions are unlikely to suffer burden or harm (physical, mental, psychological, spiritual or social).

The National Health and Medical Research Council QA guidelines clearly state that ethics approval is not required for QA programs. Institutional approval was sought from Arthritis Western Australia and from the Advisory Committee regulating the implementation of the OAK study (see attached documentation) both of which ratified this as a QA program.

4. Because Australian regulations state that "consent may be expressed orally, in writing or by some other means (for example, return of a survey, or conduct implying consent), depending on: (a) the nature, complexity and level of risk of the research; and (b) the participant’s personal and cultural circumstances", we recognise that verbal consent can be adequate. Please confirm that the HREC of AWA gave explicit approval for verbal consent to be used in this trial.

Both Institutional bodies gave explicit approval for verbal consent to be used in this QA program.

**Reviewer's report**

**Title:** Long and short-term effects of an education self-management program for
individuals with osteoarthritis of the knee, designed and delivered by health professionals: a pilot study

Version: 6 Date: 16 May 2008
Reviewer: Elaine Thomas

Reviewer’s report:
The authors have addressed the majority of the points I raised in the previous review of this manuscript. However there are some points that have only been partially addressed and some that have not been addressed. In addition, some of the changes to the manuscript have results in additional points – these are all outlined below.

Major compulsory revisions
1) The authors have not responded, either in the revised text or the response to the reviewers, to my first point in the initial review regarding justification for their sample size (a point also noted by one of the other reviewers (Kate Lorig)). The authors report in the revised manuscript that recruitment to the study was stopped when 79 participants were recruited (page 4) but this figure is not justified.

As this was a quality assurance program a priori power calculations were not performed and recruitment was discontinued after 8 groups were recruited. An abstract had been submitted to the ACR scientific meeting and this supported the decision to discontinue recruiting and analyze the data.

2) The authors add detail regarding ethical approval (page 4) and individual verbal consent (page 5). I am surprised that the authors only gained verbal rather than written consent from participants taking part in an “experimental” study. Can the authors reassure me that the taking of verbal consent only was agreed by the body giving ethical approval?

This was a case series quality assurance program. We did not consider this an experimental study. This QA program complied with the National Health and Medical Research Council guidelines for QA programs and fit the criteria as such (http://www.nhmrc.gov.au/publications/synopses/e46syn.htm). QA programs in Australia do not require ethical approval. This has been clarified in the paper.

3) The authors now present more information on the numbers approached and taking part in the study. However, this information should be presented in the Results section, as mentioned in the previous review (Minor Essential Revision, point 1), rather than in the Methods section.

This has been moved to the Results section.

In general the authors need to ensure that information is added to the correct section of the manuscript. The Methods section should be used to report what was done and what happened during the study is then reported in the Results section. There are several additions to the Methods section in this revised version that should be in the Results section – here are some examples:

a) page 4—the whole of the paragraph starting “141 people expressed...”;

This section has been moved to Results section

b) page 4—“Participants in the OAK program were over represented in the highest group (Table 1)”;

c) page 5—“Close to 90% of the participants has other co-existing disease (Table 1)”;

This section has been moved to Results section
d) page 5—the whole paragraph reporting the data related to attendance – the Methods section should contain a description of how attendance was measured rather than what the finding related to attendance were.
This information has been added to the Methods section.
4) I assume that the authors checked the assumptions prior to using parametric RM ANOVA for all their outcome measures.
This has been clarified in the manuscript under Statistical Analysis.

5) The authors now present information from the RM ANOVA and the baseline to 12 month comparison for the WOMAC and the SF-36 in Tables 2 and 3. To further clarify the data regarding baseline to 12 month change, ie the last 3 columns in these tables, the authors should slightly re-word their description for 2) to confirm that the CI relates to the figure given in 1), ie “2) 95% CI for improvement at 12 mths”
These changes have been added to the tables

6) The authors have now added some contextual data regarding socio-economic status and clearly show that the people taking part are over-represented in the highest socio-economic group, ie 74.5% of the participants are in the top 25% of the index used. The authors need to discuss the implication of this regarding whether the program would be as effective in a group with a greater socio-economic mix.
A statement regarding this has been included.

Minor essential revisions
1) The authors report in the Statistical Analysis section that they to use RM ANOVA to assess change in the variables of interest over time. They need to add to this section that they have also examined the data from baseline to 12 months with the parameters of interest being 1) mean change, 2) 95% confidence interval for mean change and 3) effect size.
This has been added under the Statistical Analysis section.
For the effect size the authors need to explicitly state which effect size calculation they have applied paying particular attention to what method has been used to calculate the pooled standard deviation component of the equation. There is some controversy regarding which is the most appropriate standard deviation measure to use when calculating an effect size for dependent data such as is presented here (see http://web.uccs.edu/lbecker/Psy590/es.htm).
An explanation has been included in the Statistical Analysis section.
2) The third sentence in the 4th paragraph in the Results (page 7; “The subset of 34...”) needs some attention as it currently does not make full sense.
Have amended this to be more coherent.
3) The mean score for the Mental Health component of the SF-36 is missing for the 6-month follow-up data in Table 3.
This was right next to the SE and so was not immediately apparent - it is now positioned it so that it is on a separate line.

Discretionary revisions
1) There are some inconsistencies regarding the accuracy of the figures presented in Tables 2 and 3. In Table 2 the mean values are given to 1 decimal place (dp) whereas the SE are given to 2 dps and in Table 3 both mean and SE
are given to 2 dps. For consistency, I would suggest that all mean and SE values given in Tables 2 and 3 are given to 2 decimal places even if the values added are 0, eg for Physical Health in the SF-36 at 8 weeks the mean value should be 52.00

This has been amended so that all values are to 2 decimal places.

2) I am not in favour of the use of the ± symbol when presenting means and SD or SE. I prefer the use of parentheses so would suggest that in the text (page 4) to use.

These symbols have been replaced with (SE)

“… participants (19 men, 60 women, mean (SD) age 66 (9) years) had …” and in Table 1 “Age (mean (SD) years)” “66(9)”

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

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

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

Reviewer's report

Title: Long and short-term effects of an education self-management program for individuals with osteoarthritis of the knee, designed and delivered by health professionals: a pilot study

Version: 6 Date: 26 May 2008

Reviewer: Marta Buszewicz

Reviewer's report:

I think the amended version of this paper is much improved and reads more lucidly. In particular, the tables showing the results are much clearer.

I was, however, a little perplexed about the constantly changing number of people recruited to and completing the study, which was different in both versions of the paper I received. (Initially 71 enrolled / 68 completed the programme, while in the revised version 79 were said to be eligible with 69 completers ?) , Although this is a relatively minor point, it can raise some queries about the results in general, and it would have been helpful to know why these figures had changed.

79 people enrolled in the OAK program (including those who were drop-outs along the way). The 68 people represented in the results are those participants who enrolled in the OAK program and attended all the assessment time-points to 12months. The text has been amended to clarify this. The data was completely checked against hard copy to avoid any discrepancies.

In my initial review I only suggested minor discretionary, rather than any major alterations. All the points I raised have been answered, apart from my suggestion that it might have been interesting to have a little more discussion from the authors as to why they consider the results from their professional led intervention for people with OA to be so much better than the majority of the results from lay-led self-management interventions.
These have been included in the Discussion section

**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