Reviewer's report

**Title:** Exploring integrative medicine for back and neck pain - a pragmatic randomised clinical pilot trial

**Version:** 2  **Date:** 12 June 2009

**Reviewer:** Suzanne McDonough

Reviewer's report:

I have am delighted that the authors found my comments helpful. I have had the opportunity to review the authors’ comments and the revised manuscript and there is greater clarity in the paper. However I think that some further revisions are advisable.

**Major Compulsory Revisions**

I think the research team may have misunderstood my comment about looking at clinically important differences as opposed to statistical change. By this I meant that they should explore defined minimally clinically important differences (MCID) between the groups, see the comment also by Dr Poitras (point 4) for the SF36. So for example do any of the changes that you see in Table 2 for the SF36 exceed the between group MCID? At the moment it is difficult to interpret the findings, are the differences for some of the measures of the SF36 meaningful from a clinical perspective? You should also explore the other validated outcomes that you used to see if they have a published MCID? The section in the results and subsequent discussion should be rewritten in light of this, so for example is your statement on page19 true i.e. there are promising clinical differences? The team should also consider whether a different set of or additional validated outcome measures should be used in a main trial.

The discussion then needs to reflect the findings in terms of MCID above

One of the other reviewers highlighted the issue around the outcome measures used in this study, and although the SF-36 was used, it would seem that the other measures used were not fully validated. I think that the research team should seriously reconsider the outcomes that they might use in a main trial, it is not good practice to adapt any outcome measure without additional validity testing (particularly if it is going to be used as the primary outcome measure). I take on board the comment on page 7 about wanting to use tailored outcomes, and perhaps they could consider Mymop for a main trial. They need to address this in their results and discussion section, as in order for the results of a main trial to be taken seriously the choice of outcomes is very important.

Although these is now a more detailed description of the therapies used in the IM model. There is no real detail given on the treatments given in the conventional care group-on pages 12/13, 25% were referred to physiotherapy, and of the 85%
who received advice, 37% received this advice from a physiotherapist?? Can you please clarify exactly what you mean here? Also did you record exactly what the physiotherapist did with the patient, if not, this would need to be included for a main trial so that you know exactly what you are comparing between the groups.

Other specific suggested corrections:

Page 2, last sentence: change to ‘Trends in clinically’
Page 3, line 9, change to ‘Trends in clinical’
Page 3, first sentence last paragraph, add in ‘few’ between ‘last’ and ‘decades’
Page 6, line 5, insert ‘the’ between fulfilled and inclusion
Page 10, 2nd paragraph, I don’t understand the use of the word ‘booted’
Page 11, 4th last sentence, remove this sentence on approaching statistical significance, it is either significant or it isn’t plus remove from page 16.
Page 12, 1st paragraph, change word ‘reversely’ to ‘conversely’
Page 12, 2nd paragraph, fourth line add ‘the’ between ‘applying’ and ‘same’
Page 14, 2nd paragraph line 1 change ‘recruiting’ to ‘recruitment’, line 5, reword to ‘may however be an over estimation due to logistical barriers which prevented us from making direct comparisons..’
Page 15, line 2, change ‘a’ to ‘one’
Last paragraph, first line, change advert to ‘adverse’

**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