Reviewer's report

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

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Reviewer: Suzanne McDonough

Reviewer's report:

Major Compulsory Revisions

Thank you for asking me to review this interesting paper which appears to be a follow on from the piece of work published in 2007 by this group (Sundberg et al, 2007). The 2007 paper described the development and implementation of an integrative medicine model in primary care.

I would have expected that the next stage of answering this research question would be to test the feasibility of using the model compared to current care, however the aim of the current paper, identified on page 4 of the introduction, was instead ‘to explore the general effectiveness of the developed IM model compared to conventional primary care management’. I think this aim should be revised and that the authors should present this as a pilot study which tests the feasibility of an IM programme compared to conventional care. Specific objectives might then be 1. define recruitment and retention rates to the trial for both arms 2. collect data in order to calculate the power for a main trial (and move the emphasis away from describing results in an underpowered study which is too small to be robust). 3. define the IM’s used in the IM arm 4. Test the consent and assessment procedures and collection of outcome measures etc. 5. Make a crude estimate of the size effect in both arms and concentrate on the clinical importance of the changes between the groups as opposed to statistical tests. The discussion could then be written around the lessons learned from the pilot and how this information may be used to define a main trial in which effectiveness can be robustly tested. Please see Kennedy et al (2008) for an example of a feasibility write up.

I don’t think it is appropriate that the team carried out sub group inferential analyses, the sample was already unpowered before you split the groups, and so it very unlikely to be robust. It might be more useful to look at clinically important differences?

The team have not published a detailed protocol for this pilot RCT so it is not possible to compare their assumptions in this trial with a planned protocol. However I am surprised that the team would not have predicted large variability in the outcome measures given the heterogeneity of their sample. Also given that this detail in not in your 2007 paper or a published protocol you need to include much more detail on how you decided the size of the current study (page 10), taking into account the high degree of variability you would expect from such a
heterogeneous population.

I think there are other really interesting results that I would like to see the team draw out in this paper

-Page 6, the drop out rates were quite high (esp in the usual care group) over such a short follow up period, how might they address this in a main trial? In your discussion how do these drop out rates compare to CM or conventional care trials in neck and back pain?

-which CMs were chosen, reasons for choice, were multiple CMs used?
-need to also support why you expect to see moderate to large effects between groups when many studies which compare between two active forms of treatment e.g. conventional treatments and CMs show only small to moderate effects.

-Highlight the excellent recruitment rates, why do you think this was as often trials in primary care struggle to get GPs to refer into trials. This would be a useful discussion point.

-finally I think a future trial needs to explore costs and if you have collected data from which crude costs could be estimated for this study it might help inform how you would do this for a main trial. It would be interesting for example to get an idea of how much additional treatment/CMs the integrative medicine group received, this needs to be offset against the levels of difference in clinical outcomes between the groups. It may also be useful to look at side effects if prescription medication or invasive interventions were lower in the IM group.

• Minor Essential Revisions

This is a very well written and presented paper. I only have one correction. Page 11, line 16th, change advert to adverse.


**Level of interest:** An article of importance in its field

**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