Reviewer's report

Title: Acupuncture for osteoarthritis of the knee: A pilot study for an open parallel-arm randomised controlled trial

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Reviewer: Nadine Foster

Reviewer's report:

This is a pilot study comparing acupuncture and usual GP care with usual GP care, for patients who were sampled from GP registers that had consulted with knee pain associated with osteoarthritis over the last 3 years. It is reasonably limited, but as a pilot study, it provides useful information to inform a more definitive trial.

Compulsory revisions:

1. Keep the main aims and results of the pilot really clear - these are process issues - as listed on page 4 - key objectives were to establish recruitment rate, attendance levels, loss to follow-up and the sample size for a full scale trial. If these were the key objectives then why does the outcome measure section talk only about clinical outcomes and cost outcomes? Such outcomes are the ones for the main trial, rather than the key outcome measures for the pilot. Similarly the results section should first address each of the 4 key objectives before commenting on the clinical outcomes seen in such a small pilot study. Re-order these sections in the methods, results and discussion to ensure that the 4 key objectives, suitable for the pilot study, become the focus, rather than the clinical outcomes. This will also require a refocus in the abstract.

2. Usual care terminology: it is less than ideal to use this term without clearly defining it, I think the most appropriate would be 'usual GP care'. Define this the first time it is used and then use it consistently throughout the paper. The data capture on usual GP care is limited in the paper, as we do not know what medications patients were taking (this is the most common treatment offered by GPs for this patient population) or what proportion were referred on to other key professionals such as physiotherapists, exercise therapists, dietitian or nutrition staff etc.

3. The key argument made by the paper is that there is insufficient evidence on whether the clinical benefits of acupuncture are sustained in the longer-term. Although the pilot is not powered to answer that question, the data suggest there is NO difference between groups at 12 months follow-up. Despite this, the authors then state that the pilot provides evidence that a fully powered study to explore the longer-term impact of acupuncture would be worthwhile. This needs more careful discussion, to ensure the decision-making is clear.

Minor improvements:
- ensure the abstract addresses the 4 key objectives clearly, rather than focuses on clinical outcomes.

- since 2008, we now have national NICE guidance that talks about CORE treatment including advice and education, weight loss and exercise for ALL patients. Do what extent might this influence the design of the future trial comparing acupuncture with usual care? Could the discussion reflect on this?

- the loss to follow-up was substantial in the usual care group and this will seriously undermine a future trial. What steps have the authors considered to reduce the loss to follow-up other than further reminders to complete questionnaires etc? Could these be added to the discussion?

- is reference 22 on page 5 correct?

- could the authors clarify the timing of the follow-ups? They talk about baseline, 3 months and 12 months, but I think that 3 months is NOT 3 months after treatment completion but 3 months after baseline assessment. Thus 3 months follow-up is about the time of treatment completion? If so, this could be renamed to baseline, treatment completion and long term follow-up. One interpretation of the clinical outcome data would then be that acupuncture does not have carry over effects after treatment completion, and thus one might argue that the design of a future trial needs to include a treatment group that receives top-up treatment sessions over the longer-term. Might the authors consider this as part of their discussion?

- under statistical analysis, it is not clear which outcome variable was used to calculate the sample size needed for the full trial - this needs stating. Is it WOMAC pain or WOMAC global?

- the authors talk both of a future trial but also about trying to work out 'trajectory of recovery in this patient group'. An RCT is not the ideal way to study this, rather a large observational cohort followed up over time would be more ideal.

- the graphs have been cut, in terms of full WOMAC scale points, and this makes the differences between groups more marked. I suggest using the full WOMAC scales for these graphs, thus the differences between groups will look more realistic.

- all graphs and tables needs to ensure accurate wording ie. usual GP care plus acupuncture, versus usual GP care (not acupuncture v control).

- Table 2 provides data on usual GP care but does not provide the information about medication type, nor referrals to other services etc. The authors relied on self-report only to determine usual care when other sources of data (eg. medical record review) might have also been useful. Something to discuss perhaps?

- Table 3 and 4 should be ONE table, plus remove the 'total' columns from all tables as they are not useful.

**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 have no competing interests