Author's response to reviews

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

Authors:

Harriet Lansdown (harrietlansdown@gmail.com)
Katie Howard (katiedrawoh@hotmail.co.uk)
Stephen Brealey (sb143@york.ac.uk)
Hugh MacPherson (hm18@york.ac.uk)

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Author's response to reviews:

Responses to Reviewer 1
21st Sept 2009

Title: Acupuncture for osteoarthritis of the knee: A pilot study for an open parallel-arm randomised controlled trial
Version: 2 Date: 19 August 2009
Reviewer: Marlene Fransen
Reviewer's report:
Major Revisions:
1. Table 3: values for Outcomes at 3 months are identical to those listed for 12 months?
   This has been corrected
2. Figure 2: Y axis extended to 0-20 (full score range)
   Figure 3: y axis extended to 0-96 (full score range)
   We have added the range to the title of these two figures.
3. Title: Acupuncture for knee pain. A pilot study.....
   (Unless recruits are selected on established OA knee diagnostic criteria)
   Later in introduction you can allude to fact that most people aged 50 and over with chronic knee pain, the pain will be attributable to OA.
We have retained “osteoarthritis of the knee” in the title on the basis that most people over the age of 50 with chronic knee pain do have OA of the knee, our selection criteria included both knee pain and OA of knee, and our key outcome measure in this study was the Western Ontario and McMaster’s University Osteoarthritis Index (WOMAC). However we accept that without the radiographic
confirmation, having only osteoarthritis on the title may be misleading. Therefore we propose to have the title “Acupuncture for knee pain and osteoarthritis of the knee”.

4 Delete last sentence, second paragraph, in the Introduction.
Not referenced - simply your opinion.
We have removed this sentence as requested.

5 Third paragraph of Introduction. It is very counterintuitive that effect sizes would be larger for meta-analysis evaluating acupuncture against an active comparator (usual care alone) versus a placebo comparator. Please add some explanation for this finding. Please clarify that placebo is sham acupuncture, so these are studies where patients are blinded, versus unblinded studies (most vulnerable to bias).

We have added the point that a larger effect size for acupuncture vs. an active (usual care) comparator is counter-intuitive along with an explanation. We have also added whether the comparisons are with blinded or unblinded patients.

6 This may be the reason for the NICE recommendations? The additions of 95% CI around the effect sizes is also warranted.
We have added 95% CI around effect sizes.

7 The fact that two large RCTs demonstrated no difference between sham acupuncture and TCA should not be dismissed by you. In meta-analysis, several biased studies can influence the aggregate findings markedly.
We have emphasised the pooled data from rigorously conducted meta-analyses on the basis that these data provide a useful background to the present study. We believe it is beyond the scope of this pilot to provide an update on these systematic reviews.

Discussion
Key Findings

8 Placing a minimum pain rating for study eligibility (which is good idea) will have implications for recruitment rate and number of required collaborating GP practices which you need to discuss. What percentage of your recruits would have been ineligible?

We agree, and have accordingly selected a minimum cut-off point from the literature, identified the proportion of our recruits that would have been eligible, and replaced our primary care list size calculations. Please note that we have made a minor amendment to the sample size calculation, based on evidence that we have found on why the WOMAC pain scale is a better one for a primary
outcome measure than the WOMAC Global scale. This results in a small modification to the overall sample size, reducing it from 388 to 350. The rationale is set out in the manuscript.

Comparisons with other studies

9 This paragraph is a repeat of the introduction. Delete from discussion.

The two paragraphs make distinct points that are relevant to the section of the manuscript to which they relate. The introduction paragraph stresses the need for new evidence, and the discussion paragraph focuses on a comparison between our study and the existing literature. Inevitable some of the same studies will be referenced, but the context is different.

Minor Essential Revisions

10 Still no evaluation of co-morbidity in the outcome measures. There are validated self-report measure of co-morbidity that could be used with your mail-out method of data collection.

In the “Future Research” section of the discussion we discuss co-morbidities in the context of the need to take these into account, and we reference the current NICE guidelines.

11 The term ‘data’is plural, not singular. eg. baseline data are presented...

Change throughout manuscript.

This has been corrected.

12 Many sentences are far too lengthy and cumbersome. Breaking up into two sentences will increase readability.

We have broken the more cumbersome sentences up where this improves readability without loss of clarity.

Key Findings.

13 Second sentence needs correcting to: ... we found that 23% of patients identified on a York-based GP database as eligible agreed to be recruited.

This has been corrected.

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

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.
Declaration of competing interests:
I declare that I have no competing interests