Author's response to reviews

Title: Impact of singing lessons on health status in patients with chronic obstructive pulmonary disease; a randomised controlled trial

Authors:

Victoria M Lord (v.lord@rbht.nhs.uk)
Victoria J Hume (v.hume@rbht.nhs.uk)
Julia L Kelly (j.kelly@rbht.nhs.uk)
Phoene Cave (phoene.cave@ntlworld.com)
Judith Silver (info@judithsilver.com)
Maya Waldman (singingforeveryone@googlemail.com)
Chris White (chris@chriswhite.info)
Cayley Smith (cayleys@yahoo.com)
Rebecca Tanner (r.tanner@rbht.nhs.uk)
Melissa Sanchez (m.sanchez@rbht.nhs.uk)
William D-C Man (w.man@rbht.nhs.uk)
Michael I Polkey (m.polkey@rbht.nhs.uk)
Nicholas S Hopkinson (n.hopkinson@ic.ac.uk)

Version: 4 Date: 30 September 2012

Author's response to reviews: see over
Singing classes for chronic obstructive pulmonary disease: a randomized controlled trial – response to reviewers 19-9-12

**Reviewer’s report**

**Title:** Singing classes for chronic obstructive pulmonary disease: a randomized control trial  
**Version:** 2  
**Date:** 2 September 2012  
**Reviewer:** Ellen Freiberger  
**Reviewer’s report:**

The revised paper “Singing classes for chronic obstructive pulmonary disease: a randomized control trial” has undergone some changes but still some issues should be addressed.

**Major Compulsory Revisions**

1. Addressing the 2nd point of my former review (length of intervention) the points raised by the authors do not satisfactorily answer the point. Based on previous research findings with no significant findings it does not seem logic to increase the intervention length for only two more weeks and still not getting any significant findings. The argument by the reviewers to fit the intervention into clinical practice does not seem sufficient. Are there any health care regulations for COPD therapy regarding time frames then this regulation should be mentioned.

The duration of the intervention was increased for the reasons described on page 5 of the introduction and on page 15 of the discussion. As discussed a period of 3 or 6 months or an indefinite period of singing teaching might have yielded different results but we were interested in the results of a finite, pragmatic or real world intervention and that is the trial that we performed. An 8 week intervention is also equivalent to the usual duration of pulmonary rehabilitation classes.

2. Even so the objectives are now stated more clearly major issues remain. As stated in the introduction part last paragraph the term health status is used but later in the intervention part (last paragraph) it becomes clear that the SF 36 is taken for health related quality of life as an outcome but not health status. Therefore either the objective should be changed to health related quality of life investigation and also mentioned in the title. As the title states now, singing is investigated on COPD (e.g. control of breathing or functional capacities) and not on health related quality of life.

The SF-36 is conventionally considered to be a measure of health status and we consider “Health status” and “health related quality of life” to be synonymous.

3. Based on the above comments authors should change the title for not misleading the reader (e.g. Comparison two different interventions on COPD: a RCT).

We have changed the title to be more informative and it is now “Impact of singing lessons on health status in patients with chronic obstructive pulmonary disease; a randomised controlled trial”
4. Another issue now evolves regarding physical activity (PA). The authors state in the methods part baseline assessment last paragraph that each participant was given a Sensor Wears Pro prior to commencement of intervention and after completion of intervention. Based on the large difference at baseline data no arguments are given why the film group did decrease their PA after the intervention. Based on the study end (February 2011) this could be related to the winter weather and not actual PA level.

Baseline differences between physical activity measures were not significantly different between groups at baseline and the changes in these measures were not significant either. Page 15 para 1 states that this is likely to be due to a lack of statistical power and we do think that expanding this discussion would be speculative and unhelpful. Since the trial is controlled weather conditions would not explain differences between groups but may contribute to the general variability of the measurement.

Discretionary Revision
1. The authors should also state some possible arguments/pathways for the differences in the ISW between the SG and the FG after the intervention.

These differences are not significant either statistically or clinically so discussion in this area would be unhelpful.

**Level of interest:** An article of limited interest  
**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
Reviewer's report
Title: Singing classes for chronic obstructive pulmonary disease: a randomized control trial
Version: 2 Date: 17 September 2012
Reviewer: Stephen M Clift

Reviewer's report:
I continue to be concerned that the confounding inherent in the way in which this trial was set up may significantly compromise the conclusions reached. It appears that members of the the singing groups met for 16 up to sessions, whereas the members of the film group met on up to 8 occasions. Not only are the intervention and control conditions different with respect to the opportunities for socialising, it must surely also be the case that the participants in the singing groups had to travel to and from the groups twice as much - with all the physical effort involved in doing so. I am not persuaded that the two activities were comparable with respect to socialising - and therefore the intended control is suspect - but I feel that an additional bias was introduced by having twice the number of sessions for singing. The potential biases here should be more fully addressed and arguments marshalled as to why these issues do not compromise the conclusions reached. The last paragraph before the Conclusion addresses the issue of ‘dose’ of social interaction, but I don’t really follow the point made in the second sentence.

The point of the second sentence which we have expanded to make it clearer is that since the qualitative interviews with the film group revealed that they did not feel any physical effect at all from participation in the film sessions it seems unlikely that doing twice as much of it would have produced a different result.
It now states:

“A limitation of the study is that the singing group was twice weekly and the film discussion weekly which may have influenced the “dose” of social interaction with the singing group spending more time in the group activity. However, the qualitative data suggest that both interventions had social effects of a similar nature but that participants in the film group experienced no “physical” effect, making it unlikely that there would have been a different outcome if the film group had met more frequently.”

I note that a change was made to the analysis of the results by undertaking covariate analysis, but I think that some discussion is warranted regarding the clear differences between the groups at baseline across a range of indicators which suggest that the singing group was less well. I am also puzzled by the fact that the trial is said to be powered at 90% to detected a difference of 10 points on the primarily outcome measure, but that at baseline the groups differ by no less than 14 points on this measure. I am not clear why a difference this large should be statistically insignificant and for that reason I recommend that the paper be
reviewed by a statistician.

Numerically the singing group were somewhat worse for their baseline differences but these were not statistically significant. The trial was powered for change in health status and the outcome is significant because the direction of change was consistent and these

Some minor points that need attention:
References 14 and 15 are cited as showing that singing can be beneficial for people with chronic health issues - but neither paper is concerned with singing

These have been removed

Over what period did the singing groups run? I appreciate that there was a 'rolling programme', but given the numbers in total in the study I think it would help to know this, and also how many people on average attended singing groups. The experience for singers of being in a group of 15 is very different from being in a group of 3. Similarly, it is important to have a clear idea of the numbers of people in the film groups on average. You note in the revision that 18 films were shown, and given that there were 11 people in the film group arm of the trial, this suggests that some of the discussion groups would have been quite small.

That is an interesting point - there were usually 4 to 6 people in the sessions and this is now mentioned in the discussion as a potential factor to consider in future trials (Page 16 para 1).

Level of interest: An article whose findings are important to those with closely related research interests
Quality of written English: Acceptable
Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.