Author's response to reviews

Title: A cluster randomised controlled trial evaluating the effectiveness of a structured pulmonary rehabilitation education programme for improving the health status of people with chronic obstructive pulmonary disease (COPD): The PRINCE Study.

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Version: 2 Date: 22 December 2010

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Reviewer: Huib Kerstjens

MAJOR COMMENTS

1. I could not find the number of patients to be included. The current statement is “Sample size calculations estimate that 32 practices with a minimum of 10 participants per practice are required, in total, to be randomised to control and intervention arms for power of at least 80% with alpha levels of 0.05, to determine a clinically significant change of 0.5 units in the CRQ.” It may be my unfamiliarity with cluster randomization, but I think the reader can and should be informed more.

Our sample size calculations are reported in line with recommendations from the extension to the CONSORT Statement for cluster randomized trials (please see http://www.consort-statement.org/extensions/designs/cluster-trials/). This recommends that the number and size of each cluster is reported. Within this section we also report the assumptions we used in our sample size calculations including power, alpha, intracluster correlation (ICC) and attrition. It would not be reasonable for us to state the total number of participants in the control and intervention groups as this is largely dependent on the number of clusters. On this basis, and based on our adherence to the CONSORT extension, we have not altered this section. We are however open to any suggestion the reviewer or editor may have on how we might improve this section.

2. Aim 3, as currently written is not very appealing (To understand participants’ perceptions and experiences of ‘COPD’, its impact on their lives and their approach to self-management). I would think a lot of this is known already. Along these lines, the description of the qualitative sub-study starting on page 12, is not very appealing. The first aim on page 13 is to me non-descript: “determine the components of usual care for both the intervention and control groups.” The sampling criteria at the bottom of page 13 and 14 I believe are vague. The level of balance should be given: not only the fact that patients from both categories will be included is useful, but for instance that half of patients will be from both categories; or at least 33% or so.

We agree that much has been written on these issues. However, most studies are descriptive or phenomenological in nature. Relatively few studies have sought to “understand” the meaning of COPD for and to the person, nor have they explored in depth broader issues, for example, approaches to self-management, limiting activity or the evolvement of self-management strategies. This element of the PRINCE study will aim to develop a theory to further develop what is written on this area. Hence, the selection of grounded theory as the methodology for this study.

3. I am worried that if the intervention arm has a larger quality of life after 12-14 weeks, the interpretation needs not be that SPREP works so well, but that all the extra attention and many visits to the practice improve QOL. What do the authors
think of this? It could be added to the manuscript already in the current protocol description-phase.

The paper currently notes that ‘The experimental group will receive the structured education pulmonary rehabilitation programme (SEPRP)’. It is noted further that this ‘…consists of an eight-week programme with a two-hour session each week (16 hours total duration) delivered jointly by a practice nurse and physiotherapist.’ Thus, weekly meetings with the practice nurse IS part of the intervention i.e. SPREP. We are not seeking to evaluate individual components of SEPRP but rather the entire programme. If there is a beneficial effect in outcomes for participants in the intervention arm we will be able to conclude that SEPRP is effective but will not be able to conclude what specific components of SEPRP contributed most to such effectiveness. We have added this to the paper as requested.

4. I might have missed it, but I think a clear statement should be made on who has access to the data-base, especially since there is sponsoring involved. Similarly, a statement on declaration of clean file and data-lock before any analyses are made, should also be in the manuscript.

We have revised the manuscript accordingly.

5. The authors should comment in the manuscript on their expectations of the cost-effectiveness analysis. Given the very short follow-up period of only 14 weeks, the costs will be large (provision of the intervention programme, and time invested by patients) and the potential gain in less health resource not yet perceivable.

We have revised the manuscript accordingly.

MINOR COMMENTS
1. I was surprised by the lack of mandatory obstruction (FEV1/FVC) in patients with BMI > 30. This is not very usual, and should be detailed more. Preferably refs given, and explicitly stated what inclusion criteria these obese patients must nevertheless adhere to.

We have now included justification as to why we altered the spirometry inclusion criteria for those with a BMI > 30.

2. On page 10, the following sub-sentence is unclear to me: "adjusting for clustering by inflating sample size estimates by the design effect given"

Our apologies. The second part of this sentence had been erroneously omitted. We have now amended this.

3. On the same page 10, the following is also not clear for me: "practices will be randomised in four groups on a 1:1 ratio."

We have clarified this in the manuscript.
4. Is the original protocol online somewhere? I think this would be useful. I am not sure that the trial registration (at current controlled trials) has the full protocol.

No. This manuscript represents the full protocol.