Reviewer’s report

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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Reviewer: Huib Kerstjens

Reviewer’s report:

The authors report on the protocol of a fairly large study of the value of structured pulmonary rehabilitation education programme (SPREP) for improving the health status of people with chronic obstructive pulmonary disease in Ireland.

I believe the manuscript is well structured and reads well. Most of the relevant issues in this phase of describing the protocol are there.

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.

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.

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.

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.

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.

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.

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"

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."

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.

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