Reviewer's report

Title: The effect of an active implementation of a disease management programme for chronic obstructive pulmonary disease on healthcare utilization - A cluster-randomised controlled trial

Version: 1 Date: 12 April 2013

Reviewer: Annemarije L Kruis

Reviewer's report:

This study is a large cluster randomized study which tries to discover an important topic in COPD management. However, there are some major revisions and problems with this manuscript. Please add information on costs or quality of life additional to health care consumption.

Major compulsory revisions:

Methods:

Population:

1. Please clarify the population. Are you investigating on suspected COPD patients? Why did you not report on any spirometry tests or on any official diagnosis of COPD by a GP or pulmonary physician? Do you mean self-reporting of diagnosis by a patient or by a doctor? It is widely known COPD is underreported and patients don’t recognize the term"COPD". How do you account for this?

2. Please explain why you used an age of 35 years of age, and not according to current (inter)national (ie GOLD) guidelines an age of 40 years of age?

3. Please explain in more detail the COPD algorithm; was it a way to discover which patients had COPD? Please would it then not be better to explain this clearly, as it makes the reader possible to identify which steps were taken to identify COPD patients.

4. The authors did not report on the inclusion and exclusion criteria according to protocol as published on their clinical trial registry. The following in and exclusion criteria of patients are missing in this manuscript, which were reported in the clinical trial registry:

Inclusion Criteria:

• People who live in either Ringkoebing-Skjern or Ikast-Brande municipalities and have a GP in the municipality and have been in hospital during the last 5 years with a lung related diagnosis or has redeemed a prescription for medication for lung related problems twice during the last year or has had at least two spirometries done during the last year.

Exclusion Criteria:

• People who do not fit the above inclusion criteria
5. Please according to CONSORT Cluster randomized statement, try to differentiate and describe on patient and health care provider level the in and exclusion criteria.

6. The question is not well defined: is the aim of this study to analyze the effect of the disease management program on suspected COPD patients or on identified COPD patients?

**Intervention:**

7. The components, duration, and intensity of this intervention are not clear. Which health care providers were involved? Disease management is by definition a multidisciplinary and multitreatment process, please explain if any physiotherapists, pulmonologists, dieticians were involved, for example?

8. Please clarify the different components of care of your intervention in more detail. As you only refer for the content of your intervention to the submitted article, however for unknown readers you must clarify and shortly introduce your intervention in more detail.

9. Please specify, according to the CONSORT statement of cluster-randomization, which interventions pertain to the cluster level, the individual participant level or both.

**Outcomes:**

The primary and secondary outcome here are not the same as it was in the clinical trial register. In the trial register the primary outcome reported is change in COPD patients self-reported health, their evaluation of the health system and the distribution of health resources.

Clinical trial registry of this trial, found online:

Primary Outcome Measures:

- Changes in COPD-patients self reported-health, their evaluation of the health system and in the distribution of health resources. [ Time Frame: 14 months ]

Secondary Outcome Measures:

- Health professionals [ Time Frame: 14 months ] How health professionals perceive the implementation and how it influences their conception, interactions and culture.

Is it not acceptable to change primary and secondary outcome according to protocol as this introduces major important bias. Please change this section in your article and change the outcomes and results.

11. Please specify the primary endpoint. The authors stated the study provided 2008 until 2010; however why is 2010 missing in the results? Please add the data on 2010 in your tables and results.

12. Please specify if outcomes were measured at patient level or GP level according to CONSORT statement.

13. Cluster-randomization:
The authors introduced noteworthy bias in different ways. Recruitment bias of cluster RCTs can occur when patients are recruited to the trial after the clusters have been randomized, especially when a poster is displayed in a GP waiting room (as is reported here). Patients with more complaints can be introduced in the active group, however these patients will not be recruited in the control group. Please explain or regard to this bias in discussion or methods paragraph.

15. Major point is how you did analyze your results, it is not clear whether the cluster size and the intra cluster effect were taken into account? You report a design effect of 1.6, please explain which ICC you used and why you chose this ICC.

17. The authors introduced bias by cross over of two intervention practices to the control group. Why did these intervention practices drop out? Were they already on good care? This can led to important bias. Please explain.

Sample size:
18. It is not clear why the authors chose for a change from 50 to 60% in a yearly follow-up consultation. Please explain.

Results:
19. The following outcomes are missing: Primary Outcome Measures:
- Changes in COPD-patients self reported-health, their evaluation of the health system and in the distribution of health resources. [ Time Frame: 14 months ]

Secondary Outcome Measures:
- Health professionals [ Time Frame: 14 months ] How health professionals perceive the implementation and how it influences their conception, interactions and culture.

20. Table 1: information on disease characteristics, as are, GOLD stage, lung function, are missing. It would be informative for the reader to know more details about the patient population and GP population.

21. Please reduce the amount of information in your tables.

22. Please reduce the number of tables to 3 in stead of 5.

23. Please think about if it is necessary to report on the whole population and the CD population as well, think about to chose one (only CD?) as you report too much information in Table 2-5.

24. Patients who died should be included in an intention to treat analyses and should not be left out.

25. Discussion and conclusions are well written compared to the other sections of this paper. However, as you only report on health care usage, without relating it to quality of life, quality of care, or satisfaction of patients and providers with care, it is not that interesting to the reader. Please I strongly advise only to publish this article when data on health care usage are related to quality of life or
quality of care.

26. No problems with title. Abstract needs major revision: Please specify in the first sentence of the methods the number of GP practices, and the number of patients. Results are not clear: to what kind of numbers of patients are the authors referring; CD? Whole population?

Minor revisions:

1. You report on a major difference in your text between home visits: 0.002 vs 0.005 with an IRR of 2.39. However 2/1000 or 5/1000 is not that large. Please report on any important differences, and not suggesting any important differences when they are not important.

2. Please clearly specify the number of practices in this flow chart.

3. The authors refer to the review of Adams et al in the discussion section and state they made a similar observation with regard to the amount of components, however for the reader it is not clear how many components there are in this intervention.

4. I strongly advise to let the manuscript be checked by a native speaker.

Discretionary revision:

1. It would be informative to give more details about the GP practices (men/women, mean age, how many years practicing), as it can be informative for the reader to know about the population.

**Level of interest:** An article of importance in its field

**Quality of written English:** Not suitable for publication unless extensively edited

**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