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

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Reviewer: Nicholas Zwar

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This is an ambitious study of a complex intervention which involves a number of elements of the Chronic Care Model and makes use of the Breakthrough Method. The inclusion of an external comparison in another municipality makes the design more complex but is understandable given that some elements of the intervention involved changes in services available in the community and may have been used by patients in the control group practices.

There are a range of issues with the conduct and reporting of the study that need to be justified if the article is to be accepted.

1. The aim of the study is described as determining whether implementation of the disease management program affected health care utilization. This leads the reader to expect measures such as use of hospital services, unplanned admissions and attendances at emergency departments but in fact the study is powered on the outcome of patients having a yearly follow-up appointment for their chronic disease. This sounds more like a measure of the uptake of the intervention than a measure of outcome of the intervention. The measures of health care utilization that better reflect the impact of the intervention are all secondary measures.

2. The COPD algorithm used to ascertain cases needs more description in the article given the well known problems with accuracy of diagnosis of COPD. How the subgroup confirmed the COPD diagnosis is not clear. A section on participants in the methods could help to better organise this description.

3. The intervention is only briefly described as a more detailed description has been submitted elsewhere but the fact that this has not yet been published makes it difficult for the reader to know what was done in this complex intervention. Given that the article has not been published the description given in this publication needs to be able to stand alone.

4. The randomisation process is a major problem. The researchers had an independent researcher do the block randomisation but then moved two practices randomised to the intervention group to the control group. This undermines the randomisation.

5. The lack of allocation concealment post randomisation is also a problem. It may have been possible to blind the project staff collecting the outcome data to
allocation group but this was not done and is a flaw in the study design. The authors need to explain why this was not done.

6. The primary analysis should be intention to treat and then a sub group analysis done of those practices who implemented the intervention. Moving practices between groups is not acceptable and is not consistent with the statement in the discussion that “the study draws strength from its randomised design”.

7. The understanding of the intervention would have been enhanced by a process evaluation component to the study e.g by conducting interviews with patients and health professionals. This may have helped look in to the black box of the intervention. The authors could comment on this as a limitation and/or a direction for future research.

**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