Author's response to reviews

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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Author's response to reviews: see over
Dear Editors,

We are very grateful to you for providing us with the opportunity to further clarify our manuscript “The effect of an active implementation of a disease management programme for chronic obstructive pulmonary disease on healthcare utilization - A cluster-randomised controlled trial”. We appreciate both reviewers’ comments, and the suggestions have been very helpful in improving our manuscript.

We fully agree that salami-publishing of scientific research should be avoided, and this study focuses on another population than our other papers as the population reported in this paper is drawn from registry data. After having performed the first editorial changes, we have two populations: one population that consists of those respondents who returned the questionnaire confirming or rejecting having chronic obstructive pulmonary disease and one population that consists of both respondents and non-respondents, i.e. the entire population defined as being at risk of having chronic obstructive pulmonary disease. We analysed data separately for these two populations.

In the patient evaluation paper, the study population comprised patients who answered two questionnaires one year apart and who answered at least 50% of the PACIC instrument in both questionnaires. The PACIC instrument was embedded in the questionnaires. Likewise, only data from the patients who have answered the questions from the EQ-5D in both questionnaires will be analysed and reported.

Outcome in this present paper is accordingly based solely on registry data. Thus, the title of our paper also clearly indicates that we are focusing solely on the effect on healthcare utilization.

If all three outcomes, i.e. healthcare utilisation, patient evaluation and economy, should be reported in a single paper, we think it would be difficult to duly explain the three different methods in the methods section and in the analysis section; many more tables would have to be included to report the results, and the discussion would be trice as long. We find that this would be far too extensive for a single paper.

We hope that the revised manuscript has become acceptable for publication.

On behalf of the authors,

Sincerely yours

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Reviewer Annemarije L Kruis

Major compulsive revisions
The authors have clarified almost all points and inserted some major text and tables. However, I feel the authors are salami-publishing their outcomes, as there is a trend to split up research results into smaller parts that are published separately, thus increasing the number of publications. I do not see at all why health care utilization, EQ-5D and the PACIC should result in three different papers as they all target the same population. Therefore I advise this paper only to be published if the authors report on all their outcomes in one paper, reducing the salami-publishing in science. If they go on at reporting only health care utilization, my personal opinion would be not to be published. I let it to the editors to decide on this point if they want to publish the paper in this version including only health care utilization or if the authors require to provide all outcomes in one paper before they can go on publishing.

Please, see above in the address to the editors.

Minor essential revisions

1. Thank you for clarifying the COPD population. However for clarity it would probably more clear to move all the text regarding your study population in one section. Now there is text about the population under “Study design” (last 2 sentences), under “Setting” (last 2 sentences) and Patients and the COPD algorithm, which makes the reader had to jump to different sections to understand the population.

Ad 1.
To further clarify the COPD algorithm and the participant population we have now changed “The Patients and the COPD algorithm” to “The COPD algorithm” which reads as follows: “The COPD algorithm was validated in a previous study which suggested that it could be used as a tool to identify patients with obstructive lung disease, primarily COPD [1]. The search algorithm was based on administrative data on hospitalisation, redeemed prescriptions for lung-related drugs and spirometries performed in the GP practice; thus, the patients had already been in contact with the healthcare system for a lung-related issue.

A prerequisite for identification was that the patient should be 35 years old or older and be registered with a GP practice in the patient’s residing municipality. The patients were identified either because they had been hospitalised during the past five years with a lung-related diagnosis, had redeemed prescriptions for lung medication at least twice during the past year or had had their lung function tested at their GP on two different occasions during the past year.”

The Participants section has been changed accordingly and now reads:” The patient population comprised 3,021 patients from the two municipalities who were identified by the COPD algorithm [1]. Among these patients, 1,819 were from the Ringkoebing-Skjern Municipality and 1,202 were from the neighbouring municipality. Of the identified patients, 2,895 had a GP in the municipality of their residence. At follow-up, 159 had died or sought research protection. All patients received a questionnaire at baseline. The study
population consisted of responders who confirmed their COPD diagnosis, called the CD population. Patients who died during the intervention period were excluded (Figure 1).”

For the sub-group analysis, we wanted to examine the efficiency of the intervention; data from the two practices that declined the invitation were therefore omitted; we called the sub-group with this distribution of patients the EI population.

All patients followed their GPs’ allocation to intervention, control group or external control group and would only drop out of the study if their GP did so or if they moved out of the municipality. No GP dropped out of the study.

2. The authors describe they didn’t have access to the spirometry data of their patients in order to select and define their population and therefore had to rely on self-reporting COPD. This is in contrast to Table 2 in which they report on the number of patients who had a spirometry performed at the GP practice in different years of follow-up, which suggests there was access to spirometry data.

Ad 2.
We would like to expand on our access to the data on spirometries. We had access to data on performed spirometries in the GP practices. GPs report such data to the Danish National Health Insurance Service Registry to be reimbursed for services provided. We did not have access to data on the outcome of the spirometry. Such data are only registered in the patient file to which we had no access.

3. Text under Methods/Participants section consists of results: whole text from “the intervention group counted 48 patients…. to (Figure 1)”. Please move to results.

Ad 3.
The part concerning the results has now been removed from Methods/Participant. In the Results section, it now reads:” The patients identified by the algorithm and those patients who also confirmed their COPD diagnosis, i.e. the CD group, are characterised in Table 2. In the CD group, the intervention group counted 458 (33.4%) patients, the control group 376 (27.4%) patients and the external control group 538 (39.2%) patients. The EI population comprised 406 (29.6 %) patients in the intervention group, 428 (31.2%) patients in the control group and 538 (39.2%) patients in the external control group (Figure 1).”

4. Typos in Methods section, patients and the COPD algorithm please check and possible change text according to this: “The patients were selected either because they had been hospitalised during the past five years with a lung-related diagnosis, had redeemed prescriptions on lung medication at least twice during the past year or had had their lung function tested at their GP on two different occasions during the past year. “For the up(p=b)-group analysis we wanted to examine the effectiveness of the intervention and
therefore allocated the patients from the two practices that declined the invitation to participate to the control group; the sub-group with this distribution of patients we called the AT population.

**Ad 4.**

The text in the Patients and the COPD algorithm has been rewritten. Please, see above in point 1.

Typo’s have been corrected and the sentences adjusted. Please, see above in point 1.
Reviewer Nicolas Zwar

Major compulsive revisions

1. It can never be acceptable in a study described as a cluster randomised trial for some of the clusters randomised to be moved between groups for the analysis. The authors are now including the practices randomised to the active intervention group who declined to take part in the active intervention group for the intention to treat analysis. Even though these practices did not receive the intervention I do not think it is acceptable to ignore the randomisation and include their data in the control group for the as treated analysis. It would be better to exclude data from these practices for the as treated analysis.

Ad 1
A concern was raised about moving the two practices that declined the invitation to participate in the intervention to the control group for an as-treated analysis where those who received “the treatment” are analysed as such and those that did not are analysed as such; we have now performed a sensitivity analysis where data from these two practices have been removed from the analysis. We would consider this a “per protocol” analysis. In the paper, this analysis is referred to as the sensitivity analysis and it is explained that the data from the two declining practices have been removed from the analysis.

2. The background section of the abstract is difficult to follow and needs to be rewritten to improve clarity.

Ad 2
To improve the clarity of the Background section in the abstract, we have rewritten it and it now states: “The growing population living with chronic conditions calls for efficient healthcare-planning and effective care. Implementing disease-management-programmes is one option for responding to this demand. Knowledge is scarce about the effect of implementation processes and the effects on patients; only few studies have reported the effectiveness of disease-management-programmes targeting patients with chronic obstructive pulmonary disease (COPD). The objective of this paper was to determine the effect on healthcare-utilization of an active implementation model for a disease-management-programme for patients with one of the major multimorbidity diseases, COPD”
The manuscript has again been reviewed for language editing by Professor Morten Pilegaard.

The tables have been adjusted and have been clarified with Flory Mae Calumpita from the editorial office to now fully comply with the journal’s guideline.