Author's response to reviews

Title: Evaluation of a tailored implementation strategy to improve the management of patients with chronic obstructive pulmonary disease in primary care, study protocol of a cluster randomized trial

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Author's response to reviews: see over
To the editors of the Trials.

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Dear Doctors Altman, Furberg and Grimshaw,

We found the reviewer comments and your suggestions very helpful and have revised our manuscript accordingly addressing all the points mentioned by the reviewer. We also have sent the revised manuscript to language correction. We believe that this paper will generate interest and influence clinical practice.

Dear Doctor Damery,

Thank you very much for reading our manuscript “Evaluation of a tailored implementation strategy to improve the management of patients with chronic obstructive pulmonary disease in primary care – study protocol of a cluster randomized trial” and reviewing it. We found your comments and advice very helpful. Please find below describing how we have addressed all the issues raised. The original text of your letter is given in italics. We also send revised manuscript and a version containing all the changes to be visible to you.

With best wishes

Maciek Godycki-Cwirko

On behalf of all the authors
Major compulsory revisions

“1. I would suggest that the authors ask a native English speaker review the protocol for readability in the English language. There are a number of stylistic, grammatical and language/phrasing errors (missing words in sentences, missing prepositions etc. – too many for me to list in my own review) which inhibit the flow of the text throughout. These would be easily rectified if a native English speaker was to review the text and suggest appropriate language changes.”

This manuscript was reviewed by a native English speaker.

“2. Abstract, background para 1: The authors state that ‘not all smokers and patients with the disease receive the recommended healthcare’. Smokers with COPD are still patients, so I wouldn’t single them out here (or I would at least rephrase to something like “Not all patients with the disease receive the recommended healthcare, particularly with regard to smoking cessation advice where applicable”)

Corrected according to suggestions.

“3. Abstract, methods section: This is too long and doesn’t give a clear account of what will be done. Ensure that the methods outlined here clearly match what is mentioned in the main body of the protocol. It is also unclear what ‘management assessment’ means.”

Abstract, methods section was shortened and made more clear. We checked methods consistency with the text body of the protocol. ‘management assessment’ was replaced by “care checklist utilization”.

“4. Background, para 1: The authors state that “It is still relatively unknown or ignored by the public as well as many healthcare providers and government officials”. a) Why would government officials be interested in COPD, and b) this is a very vague statement, which I would remove as there is no evidence provided that this is anything more than anecdotal.”

We agree, the sentence was removed.

“5. Background, para 2: “This places COPD as the third most frequent – concerning frequency – chronic illness”. This seems strange phrasing to have hyphens and ‘concerning frequency’ stated. Rework this sentence.”

Sentence: “This places COPD as the third most frequent – concerning frequency – chronic illness” was changed into: “This places COPD as the third most frequent chronic illness”.
“6. Background: There is a completely random sentence about Lodz being the third largest city in Poland at the end of para 2, which has no link to either the preceding or subsequent text. Move any description of Lodz to the part where the study setting is described and where Lodz is mentioned elsewhere.”

Sentence “Lodz is the third largest city in Poland with population of about 750 000 inhabitants with basically average mortality and morbidity, although specific health data are lacking.” was moved to the part “Study Design”.

“7. Background, para 3: There is a conflict in the description – the 5th sentence says that ‘There is no specific guideline in Poland which is designed for primary care’. The following sentence says ‘...as indicated in the guidelines for the management of COPD used by Polish physicians’. The 5th sentence therefore suggests there are no guidelines, whereas the subsequent sentence says that there are. Which is it? You can’t evaluate adherence to guidelines unless you clearly state what the guidelines are, because if there are no guidelines, what is being evaluated?’”

Thanks for pointing it out. The phrase was really unfortunate. We meant lack of one agreed guideline specific for primary health care or for other medical specialist. Still the guidelines in use contain mostly the same recommendations, which we identified and prioritized in previous work for the purpose of this trial. In this study we evaluate implementation of selected identified recommendations.

The current wording is: “There is no national consensus on the care paths, and various guidelines on COPD are used, some of which national [9, 10] and some international. However, the guidelines in use share most of recommendations that we have identified and prioritized for the purpose of this trial.

“8. Background, para 3: The authors pick out a specific finding from previous research, and say that ‘an interesting finding was that extent of program accomplishment was strongest for qualified general practitioners’. As compared to what? Unqualified general practitioners? Clarity of expression needs attention here.”

Unqualified general practitioners or rather primary care physicians in the study were internal diseases specialists and pediatricians or physicians without specialty training in general practice. We added this clarification.

“9. Background, para 4: If a systematic literature search has been done as part of the project, this should be described in the appropriately academic way rather than in vague sentences like ‘we got the impression that research on the adherence to guidelines in Poland was scarce’.”

The part of sentence: “we got the impression that research on the adherence to guidelines in Poland was scarce” was removed.

“10. The final part of background para 4 is not relevant – adherence to diagnostic criteria is not the same as adherence to management/treatment guidelines.”
We rephrased this part without removing to show what sort of data is available at that stage in Poland

“11. Background, para 5: The authors mention the TICD project but do not explain the acronym until para 6. Please spell out any acronyms in full the first time they are used.”

Corrected.

“12. Background – there is some repetition and overlap in the description of healthcare access in Poland between the beginning of background para 3 and the final para of the background section. I suggest combining and consolidating this information to avoid unnecessary repetition.”

Information has been combined.

“13. Objectives: There should only be one primary aim, hence the reason it is referred to as ‘primary’, meaning single most important.”

We corrected this part leaving one primary aim.

“14. I found it difficult to understand what the authors were describing in research question 2. Perhaps some rewording would help to make this clearer.”

We rephrased research question 2

“15. Methods, study design section: It is stated elsewhere that recruitment will take place in 18 general practices that have at least 30 adult patients with COPD. In the setting and participants section, it is stated that recruitment will take place in 18 general practices with 80 or more registered COPD patients. Please be consistent in the numbers used as this is confusing for the reader.”

We corrected description to have it consistent.

“16. Methods section: The text states that ‘some of the practices were previously involved in other studies and have established agreement with the medical university of Lodz in Poland in the field of research and vocational training’. What implications could this have for bias in the study? Presumably practices which are used to research and vocational training will be far better at adhering to recommendations than practices which do not have research and training agreements or collaborations with academic institutions.”

We had the same possible implications in mind and will address them while discussing the results of the study.

“17. Methods: How might the exclusion of GPs in targeted practices who don’t participate in the study affect the likely patient numbers? How likely is it that a lot of GPs will fail to
participate? If the authors have done feasibility or pilot work prior to this trial, here would be a good point to discuss these issues.”

We did not do feasibility evaluation prior to this trial, however considering previous research cooperation with the GPs in our research network we expect similar rates of participation. Sample size calculations showed that we would need 30 patients in each practice to perform analysis, so after corrections for response and drop outs we included the practices with at least 80 COPD patients.

“18. Eligibility criteria section, patients para: Assuming a 58% response and 35% drop out rate from 80 patients will leave 30 for the study at each practice. However, these 30 patients will receive a consent form for consent to the study. Surely drop outs will occur after this point – patients cannot drop out of a study that they have not consented to, thus the 35% drop out rate will relate to numbers greater 30 patients. I would suggest making the text clearer as to the process and the calculations that gave rise to these figures, and including the recruitment and eligibility process in the RCT flow diagram (figure 1).”

We plan to send a questionnaire and consent form to 80 COPD patients per general practice, because of assumed response rate of 58% and possible a drop-out rate of 35%, what leads to final expectation of 30 patients for analysis.

“19. Methods: The authors should say more about what the mMRC dyspnoea scale is and how it works.”

This description has been added.

“20. Evaluating adherence to guidelines in this study primarily evaluates whether or not GPs can tick a box saying they have explained something to a patient or raised a particular issue with them. However, ticking a box to say it has been done (thus indicating adherence) is not the same as it having been done properly or well. Have the authors considered that adherence does not necessarily signify quality, and how will they address this in the study?”

We agree that adherence does not necessarily signify improved quality and outcome in each individual patient. Our primary ambition was to stimulate adherence. How the intervention will address the quality and outcomes in individual patients is the secondary issue. We have planned to address it with secondary outcomes measures.

“21. Process evaluation: There is very little information given about how the process evaluation will be undertaken. Asking members of the study team for their ‘impressions of how the intervention is perceived by each team’ seems vague and difficult to quantify.”

The description has been extended with more information provided.

“22. There is very little information given about the format of the interviews and questionnaire. I would like more information to be provided about this, and how the results will inform the evaluation of the intervention.”
More information has been added.

“23. Recruitment of general practices: This information is currently given towards the end of the methods section. I would suggest that this is not the most appropriate place for it, as recruitment of practices is already addressed to a certain extent in the study setting section. I suggest reordering some of the structure in the methods section to improve the flow of the text and to place similar sections next to each other. This will avoid unnecessary repetition and will make for a more intuitively structured protocol methodology. “

Major reordering has been done according to the suggestions

Minor issues not for publication:

1. Methods, settings and participants section, general practices para: there is a typo here, the authors write assumed when they mean assumed.
   Corrected.

2. Figure 1 is difficult to interpret with dark text in dark colored boxes. I would suggest making this diagram pure black and white so that the text can be easily read.
   Corrected.

3. Figure 1 also has a couple of typos – the word ‘questionary’ is in there twice. I’m sure the authors mean ‘questionnaire’.
   Corrected.