

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Understanding influences on the uptake of pulmonary rehabilitation in the East of England: an Inclusive Design / mixed-methods study protocol
AUTHORS	Liu, Yuanyuan; Dickerson, Terry; Early, Frances; Fuld, Jonathan; Clarkson, John

VERSION 1 – REVIEW

REVIEWER	Samantha Louise Harrison School of Health and Social Care, Teesside University, Middlesbrough, UK
REVIEW RETURNED	21-Dec-2017

GENERAL COMMENTS	<p>Well done on the production of a very interesting protocol describing a novel way of approaching the complex issue of referring and delivering pulmonary rehabilitation (PR) to individuals with COPD. I am looking forward to seeing the results arising from this work next year.</p> <p>I have made a couple of comments below for your consideration.</p> <ol style="list-style-type: none">1. I am unsure why registration is not deemed necessary. Although this is not a clinical RCT you can still register the study and I would advocate doing so.2. Abstract<ol style="list-style-type: none">a. In the methods section describing step 3 I am unclear what data the framework analysis will be conducted on – is this the data collected in stage 1b (interviews with patients) and 2a (estimated care journey). Could you please add a couple of words to make this clear?3. Introduction<ol style="list-style-type: none">a. A strong rationale for why COPD and PR is a key priority at a national level is presented, however could you please add some regional statistics to the section. As the study will be conducted in a single region it would be valuable to know how the data for the East of England compares to national averages.b. The aim is currently stated: to improve access to PR. At this stage I do not believe the proposed study would meet this aim. For example the service is not being implemented and referral/uptake rates are not being recorded. I imagine this will be the next stage of this research. Instead perhaps the aim would be better described as: to provide recommendations for how primary care PR services may be improved to increase access to PR. Please consider.
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	<p>c. I wonder if the paragraph on inclusive design would be better placed in the methods section as a first paragraph labelled study design. Please consider.</p> <p>3. Methods and analysis</p> <p>a. Will more than 1 researcher be involved in each stage of the analysis? This would be necessary to improve validity and reduce risk of bias. Please consider adding this information.</p> <p>b. With regards to Step 4 I am unsure that focus groups can be used to check the feasibility of the improvements to a service that has not yet been implemented. Instead focus groups can be used to obtain the views of health care professionals (HCPs) and patients on the proposed approach. Particularly as the approach may undergo further re-development as a result of these focus groups. Please consider re-phrasing.</p> <p>c. It is important to consider the impact of interview(s) being conducted in certain locations i.e. if conducted in a PR setting patients may have cues to prompt thoughts and discussion however they may also feel obliged to talk positively about the service. Furthermore what will be the relationship of the interviewer to the patients and HCPs and what is the researcher's background i.e. profession. Please add a couple of sentences on reflexivity.</p> <p>d. Sample size is usually dictated by the theoretical underpinning for qualitative research and, in the case of thematic analysis, by data saturation. This may need to be increased as 3 sub-groups of patients are being included. Please consider.</p> <p>e. What is the rationale for collecting more data on those who have accepted a referral to PR compared to those who declined a referral or were not referred? Although it may be more difficult to engage those who have declined PR participation an interview does not have the same practical or psychological barriers as engaging in PR. Also why are people aged 50-64y not included? I believe this is an important population to collect information on as younger people are less likely to engage in PR and the early detection of COPD is advocated. Please consider.</p> <p>Minor comment(s) Please be consistent with the use of acronyms for pulmonary rehabilitation – at times the acronym PR is used and at others pulmonary rehabilitation is written in full.</p>
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REVIEWER	Andrew Wilson Norwich Medical School, University of East Anglia, UK
REVIEW RETURNED	29-Dec-2017

GENERAL COMMENTS	<p>The researchers propose a qualitative study to identify patient related barriers to pulmonary rehabilitation which appear most related to those of disability. They plan to explore the pathway to being referred for PR in some detail down to the initial phone call to the GP prior to making the diagnosis. They will then attempt to clarify the pathway their care needs and capabilities from (a minimum of 10) patients and healthcare professionals by interview then 2 focus groups. They will use these data with reference to a database of range of disabilities to find out the demands of the steps within the pathway. They will use this information to estimate the access to PR and suggest methods of overcoming the barriers. The authors have clearly (over) simplified the pathway in their</p>
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	<p>example for clarity. There are innumerate different pathways from initial diagnosis to PR referral, and although the majority can be identified by the sample they have chosen it is difficult to know when they will reach saturation. Also, some important pathways may be missed simply by the entry criteria of the study e.g. ability to read/write in English. I am not sure how the analysis will determine the frequency or importance of the main barriers within the steps of the pathway. I cannot see any reference to understanding the social context of individuals including the role of relatives and carers, or the patient demographics. Generation of the approach to improve the care journey (step 4) is going to be difficult using the data obtained in this study alone. I think that the authors should discuss some of these limitations.</p> <p>I am not aware that this approach has been utilised in the healthcare setting before. It would be useful if the authors described how this approach has been used in other settings for example within industry or manufacturing and how the other settings are similar to or different from the healthcare setting.</p> <p>The first sentence of the aims paragraph is clear, although overarching, and expanded/explained appropriately. Given that the methods of this study are complex, they could be described in more detail in the abstract and the introduction could be reduced/summarised. The authors could consider providing more details about how they think the results of the study could be used both in the abstract and the manuscript. The article summary does not really describe the weaknesses or limitations of the study in detail.</p> <p>Given that this is a protocol paper, a bit more explanation and description of the methods would be useful. I am not convinced that there is sufficient detail for the study to be replicated.</p> <p>The investigators might want to consider greater input from clinicians and individuals delivering pulmonary rehabilitation.</p>
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REVIEWER	Anne Holland La Trobe University and Alfred Health, Melbourne
REVIEW RETURNED	02-Jan-2018

GENERAL COMMENTS	<p>This study protocol addresses the important issue of poor pulmonary rehabilitation uptake. The authors propose to use Inclusive Design to assess and categorise patient-related barriers to pulmonary rehabilitation in people with COPD.</p> <p>The research question is stated as 'How can inclusive design be used to improve patients' experience of accessing pulmonary rehabilitation within the community?' I do not think the proposed study will address this, as it will not assess whether patient experience is improved. The final stage of this study will propose a new model, but the model will not be tested. As a result I think the question should be revised.</p> <p>Similarly for the title - the study will not in itself improve uptake and attendance, although it may improve our understanding of contributors. I think the title should be revised.</p> <p>The Inclusive Design approach used in this study focuses solely on patient related barriers to pulmonary rehabilitation uptake. The underlying premise is that failure of uptake relates to demand exceeding patient capability. Whilst this may contribute, much of the previous research in the area has also identified system-related contributors to poor uptake. As a result any solution that emerges is</p>
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	<p>likely to be partial. A recent systematic review has been published on this topic which details the range of contributors (Cox et al Journal of Physiotherapy).</p> <p>The study will recruit up to 15 health professionals and 15 people with COPD. These seem like small numbers across the diversity of people represented - GPs, nurses, physios, commissioners, managers, patients across the spectrum of disease severity and with various experiences of pulmonary rehabilitation. Are the authors confident that saturation could be achieved with these numbers in a group with diverse experiences and perspectives? Most previous studies have recruited to achieve saturation in relevant subgroups - eg saturation both for patients who have attended pulmonary rehab, and also for those who have not. It seems that the study will recruit in a fairly narrow geographic area, which limits the number of health professionals who are available to participate. Can the area be broadened?</p> <p>The methods require more details so that they could be replicated:</p> <ol style="list-style-type: none"> 1. The semi-structured interview questions are key to the study and should be presented. 2. It is not clear whether the scoring on the Exclusion Scales is reproducible. Is the scoring based solely on the information gained from the interviews? It is not clear how the Exclusion Calculator relates to people with COPD, as it seems to provide population estimates. 3. It is not clear how the 'new' approach will be developed - it seems a leap from the previous steps and some information on the intermediate processes would help. Given the complexity of the problem it also seems unlikely that one solution would be sufficient. 4. The new approach is described as 'validated' in step 4, but it won't actually be tested in this study, so I am not sure it should be described in this manner. <p>Minor comments How will 'stable disease' be defined? The section on research bias mentions a literature review, but it is not clear whether this has already been performed.</p>
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VERSION 1 – AUTHOR RESPONSE

Editorial Requirements:

- Please revise your title to include the location. This is the preferred format for the journal.

Response: We have included the location as suggested. Here is the revised title – “Understanding influences on the uptake of pulmonary rehabilitation in the East of England: an Inclusive Design / mixed-methods study protocol”.

Reviewer: 1

Reviewer Name: Samantha Louise Harrison

Institution and Country: School of Health and Social Care, Teesside University, Middlesbrough, UK

Well done on the production of a very interesting protocol describing a novel way of approaching the complex issue of referring and delivering pulmonary rehabilitation (PR) to individuals with COPD. I am looking forward to seeing the results arising from this work next year.

- Response: We appreciate the reviewer for the encouraging comments.

I have made a couple of comments below for your consideration.

1. I am unsure why registration is not deemed necessary. Although this is not a clinical RCT you can still register the study and I would advocate doing so.

- Response: The study is registered on the NIHR Clinical Research Network Portfolio: – IRAS 209597, CPMS ID 33565 Improving utilisation of pulmonary rehabilitation v1. We have applied registration on International Standard Randomised Controlled Trial Number (ISRCTN) and waiting for the confirmation.

2. Abstract

a. In the methods section describing step 3 I am unclear what data the framework analysis will be conducted on – is this the data collected in stage 1b (interviews with patients) and 2a (estimated care journey). Could you please add a couple of words to make this clear?

- Response: Thank you for pointing this out. The framework analysis will be used to guide the data analysis of the interviews and care journey. In the revised manuscript, following explanation has been added to clarify what data the framework analysis will be conducted on.

“Step 3 will identify the challenges of the PR service; a framework analysis will guide the data analysis of the interviews and care journey.” (Page 2)

3. Introduction

a. A strong rationale for why COPD and PR is a key priority at a national level is presented, however could you please add some regional statistics to the section. As the study will be conducted in a single region it would be valuable to know how the data for the East of England compares to national averages.

- Response: We have tried to obtain the local referral and uptake figures but there appear to be no data in an equivalent format to the national data. The best we can do is insert the rather unsatisfactory statement “Referral and attendance figures in East of England are not available but we have no reason to believe that the local figures are meaningfully different from the national figures” which we have done. Additional explanation and caveats have been added to the section on Sampling and recruitment.

b. The aim is currently stated: to improve access to PR. At this stage I do not believe the proposed study would meet this aim. For example the service is not being implemented and referral/uptake rates are not being recorded. I imagine this will be the next stage of this research. Instead perhaps the aim would be better described as: to provide recommendations for how primary care PR services may be improved to increase access to PR. Please consider.

- Response: Yes. We agree with your comment and the suggested correction has been made. The sentence now reads: “The aim of the study is to provide recommendations for how primary care PR services in the East of England could improve and increase patients’ access to PR services.” (Page 4)

c. I wonder if the paragraph on inclusive design would be better placed in the methods section as a first paragraph labelled study design. Please consider.

- Response: We have made changes according to your suggestions. We moved the paragraph related to inclusive design into methods and analysis and labelled overview of methods.

4. Methods and analysis

a. Will more than 1 researcher be involved in each stage of the analysis? This would be necessary to improve validity and reduce risk of bias. Please consider adding this information.

- Response: Yes. There are some senior researchers with expertise supervising the lead researcher in each stage of the analysis to reduce risk of bias to a level as low as possible. Some descriptions have been added at the end of Research bias.

“To reduce the risk of bias during data analysis the work will be supervised by a senior researcher. A second researcher will independently analyse the data at each stage of the analysis. The primary and secondary analysts will compare results and resolve any discrepancies. Should any discrepancies not be resolved, the supervising senior researcher shall adjudicate.” (Page 13)

b. With regards to Step 4 I am unsure that focus groups can be used to check the feasibility of the improvements to a service that has not yet been implemented. Instead focus groups can be used to obtain the views of health care professionals (HCPs) and patients on the proposed approach.

Particularly as the approach may undergo further re-development as a result of these focus groups. Please consider re-phrasing.

- Response: We have rephrased the description in STEP 4: Propose recommendations “ii) Two focus groups will be organised that include both patients with COPD and HCPs to obtain the views of patients and HCPs on the proposed recommendations.” (Page 10)

c. It is important to consider the impact of interview(s) being conducted in certain locations i.e. if conducted in a PR setting patients may have cues to prompt thoughts and discussion however they may also feel obliged to talk positively about the service. Furthermore what will be the relationship of the interviewer to the patients and HCPs and what is the researcher’s background i.e. profession. Please add a couple of sentences on reflexivity.

- Response: Some descriptions are added to study settings.

“Interviews that are conducted in a PR setting will be on a one-to-one basis to minimise any bias or any external influence. Overall the researchers will need to be pragmatic about the timing, location and other environmental factors; however, the analysts will formally reflect on the influence of contextual factors on the interpretation of the results.” (Page 11)

d. Sample size is usually dictated by the theoretical underpinning for qualitative research and, in the case of thematic analysis, by data saturation. This may need to be increased as 3 sub-groups of patients are being included. Please consider.

- Response: We have increased the number of patients and addressed more details in the section size of sample. Please see table 3: Patients accepted PR offer (n=5-7); Patients declined PR offer (n=3-5); Patients never referred (n=3-5). Some descriptions have been added at the Size of Sample. “However, the sizes of the sub-groups may be substantially smaller than the guidance discussed above. Hence to enhance the validity of the results, where practicable, the sub-group sample sizes may be adjusted during data collection to reach data saturation.” (Page 11)

e. What is the rationale for collecting more data on those who have accepted a referral to PR compared to those who declined a referral or were not referred? Although it may be more difficult to engage those who have declined PR participation an interview does not have the same practical or psychological barriers as engaging in PR. Also why are people aged 50-64y not included? I believe this is an important population to collect information on as younger people are less likely to engage in PR and the early detection of COPD is advocated. Please consider.

- Response: Thank you very much for your comments.

e1. Yes, the reason collecting less data on those who declined a referral or were not referred is they are potentially difficult to identify and to recruit, and we will try our best to recruit more to make sure the data saturation.

e2. People aged 50-64 years old are included as suggested, please see table 3 on Page 12.

5. Minor comment(s)

Please be consistent with the use of acronyms for pulmonary rehabilitation – at times the acronym PR is used and at others pulmonary rehabilitation is written in full.

- Response: The correction has been made throughout the manuscript.

Reviewer: 2

Reviewer Name: Andrew Wilson

Institution and Country: Norwich Medical School, University of East Anglia, UK

Please state any competing interests: None

Please leave your comments for the authors below

The researchers propose a qualitative study to identify patient related barriers to pulmonary rehabilitation which appear most related to those of disability. They plan to explore the pathway to being referred for PR in some detail down to the initial phone call to the GP prior to making the diagnosis. They will then attempt to clarify the pathway their care needs and capabilities from (a minimum of 10) patients and healthcare professionals by interview then 2 focus groups. They will use these data with reference to a database of range of disabilities to find out the demands of the steps within the pathway. They will use this information to estimate the access to PR and suggest methods of overcoming the barriers.

1. The authors have clearly (over) simplified the pathway in their example for clarity. There are innumerate different pathways from initial diagnosis to PR referral, and although the majority can be identified by the sample they have chosen it is difficult to know when they will reach saturation. Also, some important pathways may be missed simply by the entry criteria of the study e.g. ability to read/write in English. I am not sure how the analysis will determine the frequency or importance of the main barriers within the steps of the pathway. I cannot see any reference to understanding the social context of individuals including the role of relatives and carers, or the patient demographics.

Generation of the approach to improve the care journey (step 4) is going to be difficult using the data obtained in this study alone. I think that the authors should discuss some of these limitations.

- Response: Thank you very much for your comments. Here are some clarifications:

a. Inclusive Design approach is used to make the pulmonary rehabilitation (PR) more inclusive. In this study, a representative pathway will be mapped, and we will understand the most likely care journey that patients may go through. There may be a limitation that the PR pathway may be simplified or not all the possibilities are covered. However, as long as saturation is reached, almost all the patients will be included in the improved PR.

b. One of the limitations of this study is that the social context of individuals are not included. Patients may have carers who will help them, and they may more easily access to care, but there are still some patients who may not have carers. As the ultimate goal is to understand patients' needs and improve care, we consider patients as individuals.

2. I am not aware that this approach has been utilised in the healthcare setting before. It would be useful if the authors described how this approach has been used in other settings for example within industry or manufacturing and how the other settings are similar to or different from the healthcare setting.

- Response: Thank you for your comments.

This protocol is part of a first study into the application of Inclusive Design to healthcare processes.

The authors have published one paper that explores the role of inclusive design in improving people's access to back pain treatment. The paper has been included as Chapter 17 in the book 'Breaking Down Barriers' Springer.

The Inclusive Design approach is a rigorous user-centred approach, where the fundamental premise is that accessible and usable products or services can only be developed or implemented by first

knowing the intended users. One of the inclusive design tools, exclusion calculator estimates the proportion of the British population who would be unable to use a product or service because of the demands that it places on the users' capabilities. The tool has been widely used in measuring the exclusion of consumer products. For healthcare setting, similar to products setting, it is also important to understand use's capability and demand, so that healthcare service can be better developed and benefit more people, i.e. more inclusive. By understanding the user's capability-demand in healthcare context, it would be easier to understand their capability-related needs for care and enhance the implementation of the healthcare services.

The correction has been made in Discussion, "The Inclusive Design methods used in our study have been adapted from their original context (measuring the exclusion of consumer products) and applied to care journey analysis....." (Page 13)

Regarding how Inclusive Design approach is used, we have the detailed methods of how to use the inclusive design tool to measure the exclusion in the Study Procedures section, Step 2: Estimate Exclusion.

3. The first sentence of the aims paragraph is clear, although overarching, and expanded/explained appropriately. Given that the methods of this study are complex, they could be described in more detail in the abstract and the introduction could be reduced/summarised.

- Response: Some extra description about methods has been added in the abstract and the introduction has been reduced. Due to the word limitation of abstract, more detailed description about methods are added in study procedures and appendix.

4. The authors could consider providing more details about how they think the results of the study could be used both in the abstract and the manuscript.

- Response: We agree and have added more details about how we think the results of the study could be used in the body and to a lesser extent in the abstract due to word count limitations. In the abstract, "It aims to inform improvements to the PR service by identifying barriers to the uptake of PR in the COPD care journey, in relation to patients' capabilities, that can affect their access to PR." (Page 1)

In the manuscript, the discussion section, "A strength of the approach is that it has both qualitative and quantitative perspectives that give not only insight into how and where changes can be made but also what impact the changes might have on uptake of PR." (Page 13)

5. The article summary does not really describe the weaknesses or limitations of the study in detail.

- Response: This has been rewritten. We have considered several limitations of our study and summarised them in the revised manuscript.

6. Given that this is a protocol paper, a bit more explanation and description of the methods would be useful. I am not convinced that there is sufficient detail for the study to be replicated.

The investigators might want to consider greater input from clinicians and individuals delivering pulmonary rehabilitation.

- Response: Thank you very much for your suggestions. More description about the methods have been added in the Study Procedure (Step 2: Estimate exclusion, on Page 8-10). Topic guides and questions for the interviews and focus group are added as appendix. With these additional explanation and description of the methods, we hope that you will consider that enough information has been added. Regarding greater input from clinicians, we have involved physiotherapists who deliver PR in our research. We will focus on the pathway from diagnosis to PR programme attendance while patients' ability to do exercises and take part in PR once they are there is not the focus of this research. Therefore, we will interview more GPs and nurses who may referral patients. In addition, a Consultant in acute and respiratory medicine has also been advising us and we have taken this opportunity to include him in the review process and added him to the author list.

Reviewer: 3

Reviewer Name: Anne Holland

Institution and Country: La Trobe University and Alfred Health, Melbourne

Please leave your comments for the authors below

This study protocol addresses the important issue of poor pulmonary rehabilitation uptake. The authors propose to use Inclusive Design to assess and categorise patient-related barriers to pulmonary rehabilitation in people with COPD.

1. The research question is stated as 'How can inclusive design be used to improve patients' experience of accessing pulmonary rehabilitation within the community?' I do not think the proposed study will address this, as it will not assess whether patient experience is improved. The final stage of this study will propose a new model, but the model will not be tested. As a result I think the question should be revised.

- Response: We agree with this comment and we have taken the opportunity to rewrite the research question, which has been revised as, "how can Inclusive Design be used to improve patients' access to PR services within the community?"

2. Similarly for the title - the study will not in itself improve uptake and attendance, although it may improve our understanding of contributors. I think the title should be revised.

- Response: The title has been revised as, "Understanding influences on the uptake of pulmonary rehabilitation in the East of England: an Inclusive Design/ mixed-methods study protocol".

3. The Inclusive Design approach used in this study focuses solely on patient related barriers to pulmonary rehabilitation uptake. The underlying premise is that failure of uptake relates to demand exceeding patient capability. Whilst this may contribute, much of the previous research in the area has also identified system-related contributors to poor uptake. As a result any solution that emerges is likely to be partial. A recent systematic review has been published on this topic which details the range of contributors (Cox et al Journal of Physiotherapy).

- Response: We agree that patients' capability is only part of the reasons that affect uptake of PR service. However, as we wrote in the paper, people's personal capability to access a healthcare service is a prerequisite for them to use it. Therefore, if patients are not even able to attend PR service, the understandings of system-related contributors would be limited. Moreover, patients with COPD are likely to have limited mobility. Hence, it is very important to consider patients' capabilities in order to improve access to PR services. We have read the paper you refer to; it was useful and has been referenced and discussed in section: the evidence gap, "Most of these barriers have been identified as relating to the context or environment, people's knowledge, and patients' and clinicians' beliefs." (Page 4) In order to improve our communication of this issue we have added several comments to help clarify your valid observation and the limitations of this study in this respect.

4. The study will recruit up to 15 health professionals and 15 people with COPD. These seem like small numbers across the diversity of people represented - GPs, nurses, physios, commissioners, managers, patients across the spectrum of disease severity and with various experiences of pulmonary rehabilitation. Are the authors confident that saturation could be achieved with these numbers in a group with diverse experiences and perspectives? Most previous studies have recruited to achieve saturation in relevant subgroups - eg saturation both for patients who have attended pulmonary rehab, and also for those who have not. It seems that the study will recruit in a fairly narrow geographic area, which limits the number of health professionals who are available to participate. Can the area be broadened?

- Response: We have addressed this in the section: Size of sample, "However, the sizes of the sub-groups may be substantially smaller than the guidance discussed above. Hence to enhance the

validity of the results, where practicable, the sub-group sample size may be adjusted to reach data saturation.” (Page 11)

Your comments on geographic area are valid and so we have tightened this in the text and particularly the title by specifying the East of England. Although the HCPs and patients we will recruit are from a relatively narrow geographic area, we will recruit from both urban and rural locations to broaden the range of views available. In practice given the fact that the area we study is representative of the UK, it would be more practical to recruit HCPs with the areas that we have networks. We have included additional comments to address this limitation.

5. The methods require more details so that they could be replicated:

a. The semi-structured interview questions are key to the study and should be presented.

- Response: Yes, we agree. The semi-structured interview questions are added as appendix 1 and appendix 2.

b. It is not clear whether the scoring on the Exclusion Scales is reproducible. Is the scoring based solely on the information gained from the interviews? It is not clear how the Exclusion Calculator relates to people with COPD, as it seems to provide population estimates.

- Response: We need to first clarify that the scoring system (based on the Exclusion Calculator) is not affected by the interview data, and only the scored capability of COPD patients are results from interview data. Therefore, the scoring is reproducible. The questions for measuring people’s capability are added in appendix 3 and more details are described in step 2 - b) Estimate the number of people excluded from PR on the basis of their capabilities.

“The “Exclusion Calculator” (an Inclusive Design tool) produced by the University of Cambridge Engineering Design Centre uses a large database of British users with a range of disabilities to estimate the proportion of the British population (Great Britain) that is unable to use a product or service because of the demands that it places on the users’ capability. A version of this calculator is freely available on the Inclusive Design Toolkit website. By inputting the estimated demands of each task along the COPD care journey, the “Exclusion Calculator” can estimate the number of people within general population excluded from accessing PR (in every task and on the whole care journey). Figure 8 shows an example of measuring the hearing exclusion for the task ‘make a telephone call’. The original population data (sample size n=7618) is from the Disability Follow-up to the Family Resources Survey. Among these participants, there were nearly 1000 participants who self-reported that they have a respiratory issue and it is likely that a significant number of these people could benefit from PR. Although the exclusion numbers from the calculator are based on the general population (rather than those with COPD), we can still obtain insights about challenges raised by the COPD care journeys from the exclusion levels predicted. For some tasks, the calculator will overestimate the level of exclusion but still give useful insights as a loss in capability may not be due to COPD. Nonetheless, changes in the demand of PR on the patients with COPD will be reflected by changes in exploration from the whole population.” (Page 9-10)

c. It is not clear how the 'new' approach will be developed - it seems a leap from the previous steps and some information on the intermediate processes would help. Given the complexity of the problem it also seems unlikely that one solution would be sufficient.

- Response: To fill the gap, some information on the intermediate processes has been added in the step 2 and appendix. We agree that people’s capability may only represent a proportion of the reasons that prevent patients accessing PR. However, people’s capability is the prerequisite to access PR service, so it is important to understand patients’ capability to access the service. With a more inclusive PR service, we could have more potential patients that are able to utilise this service, and thus, we can understand more about other factors.

d. The new approach is described as 'validated' in step 4, but it won't actually be tested in this study, so I am not sure it should be described in this manner.

- Response: Thank you very much for your suggestions, we have modified the description in step 4. "Propose and refine recommendations that aims to help patients understand their needs and manage their COPD care. These recommendations could be used as an interactive tool between HCPs and patients to help HCPs to better understand patients' needs, especially the capability demand within the process of PR." (Page 10)

6. Minor comments

a. How will 'stable disease' be defined?

- Response: Stable would be defined as being free from exacerbation or hospitalisation for the preceding 4 weeks. We removed "stable disease" and have amended the wording to "free from exacerbation or hospitalisation within the preceding 4 weeks" (Sampling and recruitment - Eligibility Criteria)

b. The section on research bias mentions a literature review, but it is not clear whether this has already been performed.

- Response: The correction has been made. The literature review has been performed to design the research, but it would be clearer to remove the literature review here as we focus on collecting primary data from patients' and healthcare professionals.

VERSION 2 – REVIEW

REVIEWER	Samantha Harrison Teesside University, UK
REVIEW RETURNED	26-Feb-2018
GENERAL COMMENTS	The authors have answered most points to my satisfaction. However, I am still concerned that the sample sizes proposed will not meet data saturation and if data saturation is not reached the results can not be generalised.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1

Reviewer Name: Samantha Harrison

Institution and Country: Teesside University, UK

Please state any competing interests: None declared

The authors have answered most points to my satisfaction. However, I am still concerned that the sample sizes proposed will not meet data saturation and if data saturation is not reached the results can not be generalised.

- Response: Thank you very much for your comments. We agree the sample sizes proposed may not be sufficient for data saturation and we will adjust the number of the data collection to reach data saturation depending on the results. Some descriptions have been changed and clarified.

"The size of the sub-groups will be adjusted as necessary to reach data saturation to ensure the validity of the results." (Page 9)

VERSION 3 – REVIEW

REVIEWER	Samantha Harrison Teesside University
REVIEW RETURNED	14-Mar-2018
GENERAL COMMENTS	All my comments have been addressed. Thank you

