Author's response to reviews

Title: A pilot randomised controlled trial of a Telehealth intervention in patients with Chronic Obstructive Pulmonary Disease: challenges of clinician-led data collection

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Version: 3 Date: 3 July 2014

Author's response to reviews: see over
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Author’s response to reviews: see over
The Biomed Central Editorial Team

**Article:** MS: 1355206948126031 - A pilot randomised controlled trial of a Telehealth intervention in patients with Chronic Obstructive Pulmonary Disease

Thank you for consideration of our manuscript for publication in your journal.

We have reviewed the above manuscript according to your reviewer’s comments.

**Reviewer One Report**

**Version:** 2 **Date:** 27 May 2014

**Reviewer:** Zainab Samaan

**Reviewer’s Report:**

The authors describe a pilot RCT investigating the use of telehealth intervention in chronic disorder to assist in improving caseload management and engaging patients in their healthcare. The primary goal of the pilot RCT is to assess the potential for a full RCT testing the effectiveness of telehealth compared to standard care to reduce re-admission rates and improve quality of life.

Overall, this is well written manuscript and has the potential to disseminate important challenges associated with complex health care delivery method to an increasing number of patients with chronic diseases (not just COPD) and ageing population. This manuscript has been revised based on reviewers’ comments as seen in the cover letter.

**Minor Essential Revisions:**

1) Study context: In the first line, please define PCT, I assume it is Primary Care Trust.

   ‘Primary Care Trust’ was used in full in the preceding paragraph, therefore we have added ‘PCT’ in brackets after this use

2) “It was recognized that a service which was delivered entirely face to face was unsustainable in the long term” this statement came without a substantial evidence as the services of face to face delivery was started in 2009 (5 years ago), it would be helpful to audit the service and test the sustainability of continuing the service.

   A full audit of the current service was carried out by the research team as part of the feasibility study, which has been written up as a separate paper and is currently under review elsewhere. The PCT commissioners made the initial approach to the research team and
provided cost and COPD discharge figures etc, so the initial drive to make the service more sustainable originated with the PCT. We have added the words 'by the PCT' in two places within this paragraph to try and make this clearer: “It was recognised by the PCT that a service...” and “A subsequent decision was taken by the PCT to introduce Telehealth...”

3) “Doc@Home”: what is the cost of using this service? How easy it is for patients to use? How reliable are the vital signs monitoring using this system?

The costs of the equipment, monitoring etc were included in the economic analysis, and ease of use is reviewed in a separate qualitative paper which is under review. The service was free to the end user and we have added a line at the end of ‘Study Context’ stating this (“Both the Standard service and the Telehealth-supported service are free at the point of delivery for its users”). However we feel to include detail around these elements in the current paper will not add to its central theme.

4) Data collection: first point “statistical team to author CB for each participant”, please define CB.

CB is the first author on the paper. Any reference to ‘CB’ has been changed to ‘the research team’

5) Data collection, point 5, demographic information: please replace “gender” a social construct with sex.

This has been done.

6) The pilot study conclusions. The authors concluded that the full RCT is not feasible based on the current pilot experience. From my reading of the manuscript, it seems that the “Standard Care” is a promising model of care, the collection of research data by clinicians is unadvisable and a dedicated research person is needed to ensure data collection according to protocol and finally patients with COPD and assumed other chronic disorders are in favour of face to face contact. It is also possible that the generation of the participants is not technologically inclined. Suggest these points to be included in the discussion. In addition, 40% of patients failed to qualify for the trial based on eligibility criteria making this pilot trial more explanatory and less pragmatic in design.

We have included or elaborated on these points in the Discussion and Conclusion.

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.
Reviewer Two Report

Version: 2 Date: 1 June 2014

Reviewer: Morag Farquhar

Reviewer’s Report:

This revised paper has benefitted from limiting its focus to the Phase II pilot RCT; the results and discussion are more relevant to its aims and objectives. The discussion section is strong. The paper would further benefit from the following (some structural, some points minor):

Revisions:

1) Title: could include an element suggesting the key findings of the pilot RCT such as a tag line referring to “challenges of an evaluation with high clinician involvement” or similar? Could also refer to it as a Phase II pilot RCT (flags it as following the MRC framework).

   A tag line has been included in the title (“challenges of clinician-led data collection”). However many of the reviewer’s suggested changes revolve around adding ‘Phase x’ in various places within the article in accordance with MRC. We have referenced the 2008 version of the MRC guidelines, which have very little reference to ‘Phases’ other than to say the previous (2000) version of the guidelines were criticised for being based around ‘Phases’ conventionally used in drug trials. Therefore we have decided not to include these terminologies as we wish to draw a distinction between drug trials and this trial of a complex intervention.

2a) Abstract: The sentence “Fifteen participants were excluded from analysis...” refers to only objective 3 presumably – if so, maybe make this clear?

   We have decided not to state in the Abstract which results refer to which objectives as the word count is limited to 350 words. We have made most of the suggested changes for the Abstract, but on this occasion we did not feel able to sacrifice the words needed to identify which results related to which objectives.

2b) Abstract: Sentence about sample size calculation needs more detail e.g. “The sample size calculation for Phase III RCT was guided by [...] the literature rather than the Phase II pilot RCT data due to considerable missing data.”

   We have not included Phase-based wording changes (see change 1 for explanation).

2c) Abstract: There needs to be consistency in how you refer to the control arm, both in the abstract and throughout the paper – sometimes it is referred to as “Standard Care”, sometimes as “standard service”, sometimes something else. The labels on the columns of Table 2 are the most helpful “Standard COPD Service” and “Telehealth-supported COPD Service”.

   Terminology has been made more consistent throughout.
2d) Abstract: Second sentence of conclusion refers to conducting the RCT in collaboration with clinical team, but the issue was particularly about data collection by clinical teams – collaboration with clinicians can be achieved without them doing the data collection – so the point needs to explain that it was the data collection that was the difficulty.

*This has been re-worded (“Although there are advantages to conducting an RCT with data collection conducted by a frontline clinical team…”). Other parts of the abstract have been altered to adhere to the 350 word limit.*

2e) Abstract: Final point of conclusion is relevant to “…the introduction and evaluation of complex interventions within clinical settings” – not just Telehealth.

*This has been altered.*

3a) Background: Second sentence: “support” should be “supported”

*This has been corrected.*

3b) Background: Third and fourth paragraphs hold a bit of repetition, particularly about preventing hospital admissions and improving QoL, and then again about self-management. Could be condensed.

*This has been done – see end of fourth paragraph.*

4a) Study Context: The local definition of early stage COPD (in the endnote) doesn’t appear to be a definition of early COPD, but more of a referral criteria as it relates to number of admissions and not disease severity. You do refer to this later in the discussion section, which is helpful, but I wonder if referring to it as a referral criteria may be better? Or removing?

*I have added this to Table 1 (referral criteria).*

4b) Study Context: I still feel this paper would benefit from a simple two-column box outlining standard care (first column) and intervention (standard care + Telehealth; second column) for easy comparison and context setting.

*This has been done – see Table 2.*

5a) The Research Programme: I would take out the overall research question section and rename this section “Objectives of Phase II pilot RCT” and focus on these objectives only.

*We have decided not to rename the section (see Change 1 explanation). We also feel that the overall research questions are important for setting the context, i.e. this is what we wanted to ascertain, therefore we followed the MRC framework in order to begin answering the questions.*

5b) The Research Programme: The paragraph starting “Study design was informed by the Medical Research Council (MRC) guidance…”: rather than refer to it as “feasibility study” instead using
“Phase I feasibility study” would reconfirm the use of the framework, similarly could use “Phase II pilot RCT” rather than just “pilot RCT”.

_We have decided not to include Phase-related terminology (see Change 1 for explanation)._  

5c) The Research Programme: I’d suggest turning the wording of the second two objectives round so that the aim of the objective is upfront, but the means of getting there (method) comes after i.e. “2) Estimate the sample size required for a full trial by using data on patient contact with...” and “3) Preliminary evaluation of the cost-effectiveness of the Telehealth intervention by analysing...”.

_This has been done._

6a) Methods: First sentence could be “This Phase II pragmatic two-arm pilot RCT was informed by the findings of the Phase I feasibility study” – again locates it clearly in the MRC framework.

_We have decided not to include Phase-related terminology (see Change 1 for explanation)._  

6b) Methods: Sentence 2: “The pilot followed...” would be better as “The pilot RCT followed...”.

_This has been done._

6c) Methods: Section headed “Recruitment”: the first sentence and bullet points would be better in the section describing the service (again could in the suggested Box) as this is not about recruitment to the trial, but about referral to the service (which goes on regardless of the trial).

_We have moved the first sentence and bulletpoints to the Study Context section._

6d) Methods: Paragraph 5 says “Participants were entered into the study on an intention to treat basis” – my understanding is that “intention to treat” is about analysis, not recruitment?

_This line has been moved to Analysis instead of Recruitment._

6e) Methods: End of paragraph 5: blinding was not possible not only due to the complex nature of the intervention but because of the study design i.e. data collection by clinicians. If data collection had been by independent researchers then single-blinding might have been possible.

_We have altered the wording – “It was not possible to blind the involved parties due to the complex nature of the intervention and the study design”._

6f) Methods: Bullet point 2: I would have thought that Research Nurses would have been cheaper than Specialist Respiratory Nurses?

_The respiratory nurses were part of the clinical team already and so the desire was to use staff resources which were already in existence. However a Research Nurse was employed later in the trial when we fed back to the PCT that there were issues with data collection._
6g) Methods: Bullet point 3: involvement of multiple partners in research doesn’t mean they have to be data collectors – although you do address this point later in the discussion.

We agree that it does not, although this consideration did form part of our justification. We have not made changes to the text based on this particular comment.

6h) Methods: Exclusion criteria: I remain unclear why “no telephone landline” is listed when an inclusion criteria that has to be met is “have a telephone landline in the home”.

This has been removed as an exclusion criterion.

6i, i) Outcome Measures: I am not familiar with SUS – can/should this be referenced?

We have added a link to the website after the first mention of SUS.

6i, ii) Outcome Measures: SGRQ is referred to in abbreviation form before being named in full.

This has been corrected.

6i, iii) Outcome Measures: Bullet point 1 on secondary outcome measures: could describe the diary as “patient-completed diary of GP visits” for clarity.

This has been done.

6i, iv) Outcome Measures: Bullet point 2 on secondary outcome measures: EQ-5D needs referencing.

This has been corrected.

6j, i) Data Collection: This section would be better driven by the data collection methods, not the measures e.g. have three bullet points, one for researcher-collected data, one for clinician-collected data and one for device-collected data? The information about the outcome measures should be in the outcome measures section above e.g. the referenced sentences describing the SGRQ and EQ5D.

This section has been re-ordered to come before Outcome Measures and rearranged in accordance with the sub-headings provided.

6j, ii) Data Collection: May be best to refer to these as “the main planned sources of data collection” – given that this proved unrealistic.

This has been done.

6k) Analysis: cost effectiveness and cost-utility: I am unable to review this section – no expertise.

Ok, thank you.
7a) Results: First sentence feels like a discussion statement/point? Could just start results from second sentence.

   *This has been done, and a version of the first line has been moved to the first paragraph in the discussion.*

7b) Results: Second sentence: suggest insert “clinical” ahead of “staff capacity” – as could suggest capacity problems in the research team too.

   *This has been done.*

7c) Results: Fourth sentence: may be better as “The findings in relation to the three objectives of the pilot RCT are outlined below”

   *This has been done.*

7d) Results: Objective 1 - Recruitment section: delete “extending” in sentence one, as is slightly confusing with the “extended” in sentence two.

   *We have altered the wording of sentence one – “with follow-up for six months post intervention data capture continuing to June 2012”.*

7e) Results: Objective 1 - sentence two say how long it was extended by i.e. “...frame being extended from X months to X months”.

   *This has been done.*

7f) Results: Objective 1 - Recruitment section: sentence commencing “Of these, 75 declined...” would be better with the middle point first i.e. “Of these, 132 were lost....” as these were “lost” prior to the refusals. I would also not use the word “lost” as it implies recruitment then withdrawal particularly in the order you currently present these points in); may be better to refer to them as exclusions? I would also make the next sentence the one where you explain why these 132 people were excluded, as this is a significant proportion. The sentence about trial acceptance rate and randomisation could then follow this.

   *The section has been re-arranged and re-worded in accordance with suggestions.*

7g) Results: Objective 1 - Protocol adherence section: the later (hugely successful) involvement of a Research Nurse comes as a surprise here – there should ideally be some mention of it in the abstract as the success of this was considerable. It ought to be in the methods section ideally too, but I can see that it is part of the results story so not sure how to advise on handling that. The huge difference in consenting and data completion rate with the RN could be highlighted further by having an additional set of columns on Table 5 so that you have one set for the clinicians and another for the RN, then an overall total.

   *As pointed out by the reviewer, it is difficult to include the RN in the methods section as this was part of the results story, so we have not done so. We have decided not to include the additional info in table 5 (now table 6) as the table is already large (the change would involve...*
an additional 3 columns) and we have already stated that data completion jumped to 100% when the RN was involved. We have added the reference to the success of using a Research Nurse in the Abstract – “Gaps in data collection were resolved by recruiting a Research Nurse”.

7h) Results: Objective 1 - Protocol adherence section: I can’t find the %s referred to in the text (para starting “As demonstrated in Table 5…”) in Table 5.

*We have provided clarification within the text of where these percentages have come from - “As demonstrated in Table 6 there were many instances of missing or invalid SGRQ data, with 56.6%, 54.2% and 28.3% valid completion rates for each respective time point (when excluding drop-outs and missing consent)”*. They are not given directly within the table but have been worked out from it.

7i) Results: Objective 1: the sentence “The completion rate for the Standard Care eight week self-report diaries was similarly...” might be better as “The completion rate for the Standard Care eight week self-report diaries (which included the EQ5D) was similarly...”.

*This has been done.*

7j) Results: Objective 1: put the EQ5D and monthly diaries completion rate data on Table 5 along with SGRQ data.

*Table 5 (now table 6) is already large and contains a lot of info, thus we decided to give the EQ-5D completion rates in the text as we did not end up using these data in the final analysis.*

7k) Results: Objective 2 - Baseline characteristics: do you have any demographics for non-respondents for comparison?

*We do not. The ethical approval for the project would not allow us to collect personal data on individuals who declined participation and so we did not collect this info.*

7l) Results: Objective 3: change the heading to “Preliminary evaluation of cost effectiveness”.

*This has been done.*

7m) Results: Objective 3 – HRQoL section: First sentence that describes SGRQ scoring should either be in method or as a footnote to Table 9. You may not then need the separate heading for this section as very short – it could all come under the overall Objective 3 heading.

*We have added the first sentence as a footnote to the table and removed the separate heading.*

7n) Results: Objective 3 – Cost-effectiveness section: if EQ-5D scores can really be imputed from SGRQ and sex this begs the question of why collect EQ-5D data at all?
Our EQ-5D data were not reliable so that is why we calculated cost-effectiveness from SGRQ. This is not standard practice in health economics but has been used in the past to make up for gaps in EQ-5D data.

7o) Results: Objective 3 – Cost-effectiveness section: the sentences describing QALYS and NHS costs should be in the methods section. This section could then start with “There was a higher mean total cost…”.

We feel it would confuse the story if this description was included in the methods section as originally we intended to use EQ-5D. Gaps in data collection (outlined under Results: Objective One) then led to the change in analysis method for Objective Three.

7p) Results: Objective 3 – Cost-effectiveness section: Tables 10 and 11 could be combined.

The tables refer to two different analyses and we feel it is clearer to keep them separated.

8a) Discussion: “In this paper we describe a pilot randomised...” could be “In this paper we describe a Phase II pilot randomised...”; again, locates it clearly in MRC framework.

We have decided not to include Phase-related terminology (see Change 1 for explanation).

8b) Discussion: Second sentence refers to “choice of outcome measures” but I don’t recall much about this in the results – it is more about the problems with data collection processes.

We have removed this part of the statement.

8c) Discussion: Last sentence of first paragraph: ends “…it has been successful in demonstrating...” could reword to “...it achieved its objective of demonstrating...”

This has been done.

8d) Discussion: Third paragraph: where you refer to the “feasibility study” you could again add in “Phase I feasibility study” to help locate it.

We have decided not to include Phase-related terminology (see Change 1 for explanation).

8e) Discussion: Third paragraph: the lack of consenting was a concern given that these were GCP-trained clinicians – worthy of comment.

We have added some text commenting on this – “This also shows that GCP training of clinical staff is not enough to ensure adherence to trial procedures, thus research processes and data collection need to be rigorously monitored throughout the trial”.

8f) Discussion: Third paragraph: I didn’t understand what was meant by the last sentence re organisational changes within the PCT would not allow continuation of the pilot to full RCT?
We have tried to clarify and give an example – “One example of an organisational change which impacted the project was the national reorganisation of the NHS, meaning that PCTs were disbanded in March 2013 and replaced by Clinical Commissioning Groups (CCG)”.

8g) Discussion: Fourth paragraph: “The waiting list for admission to the discharge service, which began to build in month four of the pilot trial due to an unanticipated 60% reduction...”, could be “The waiting list for admission to the discharge service, which began to build in month four of the pilot trial due to the unanticipated reduction...”

This has been done.

8h) Discussion: I agree that the local definition of early stage COPD tells us little about disease severity; it is rather odd. I’m not sure if it is more confusing having it in the paper at all.

We understand your point - however this local ‘definition’ was the basis for one of our inclusion / exclusion criteria and supports the argument that we do not yet know which patients might favour telehealth.

8i) Discussion: Second last paragraph: could reference the MRC framework in the first half of the first sentence.

We have decided not to include Phase-related terminology (see Change 1 for explanation).

8j) Discussion: Second last paragraph: not clear what you mean by the second half of the last sentence. You can involve frontline clinicians in research without them being data collectors (and you do allude to this in the next paragraph although I wasn’t clear whether you were referring to frontline clinicians here or managers? Need to involve both).

We have provided clarification around these points.

8k) Discussion: Last paragraph, last sentence: confuses complex intervention implementation with complex intervention evaluation?

We wanted to say that the needs of complex intervention evaluation and implementation are often in conflict – we have clarified in the manuscript (“the drive to demonstrate population based benefit through evaluation of complex interventions does not necessarily equate with the demands of implementing a complex intervention in situ”)

9a) Conclusions: Signpost MRC framework again e.g. “We were able to complete an informative Phase II pilot RCT despite...” and “…precluded progression to a full Phase III RCT...”

We have decided not to include Phase-related terminology (see Change 1 for explanation).

9b) Conclusions: Last sentence: the research staff don’t have to be clinical – they could be University-employed Research Assistants. The key here is that they are dedicated research staff.

This has been altered to ‘dedicated research staff’.
10) Endnotes: the key here is “a” and “*” - is this a typo. You have used “*” as a bullet point marker throughout Table 2 – so this is confusing.

   *This has been corrected.*

11) Table 1: could this list include the “definition” of early COPD – that reference to the number of admissions?

   *This has been added.*

12) Table 2: 8 month follow up row: you could put “Measurement of outcomes (postal return)” then list SGRQ, EQ-5D and GP visit record, rather than putting “(postal return)” after each.

   *This has been done.*

13) Table 3: would be helpful to say what the base number is for the %s – it looks like it is the 450 referred to the COPD service, but should it be 270 (i.e. those that met the inclusion criteria)?

   *We have changed the base to 270 and included it within the table.*

14) Table 4: what do you mean by “invalid” – as opposed to missing?

   *We have added a footnote to the table to explain this – “Not enough completed questions to generate a valid score”.*

15) Table 8: should the heading refer to p=0.05 rather than p-0.05?

   *This has been corrected.*

16a) Figure 1: Currently labelled as Figure 2, should be Figure 1.

   *This has been corrected.*

16b) Figure 1: The box of excludeds says “Other reasons*”, what does the “*” mean? Typo?

   *This has been corrected.*

17a) General punctuation needs checking: Sometimes “;” is used where “:” would be more appropriate e.g. when listing inclusion/exclusion criteria.

   *This has been corrected throughout.*

17b) General punctuation needs checking: A couple of full stops missing e.g. end of paragraph on analysis of primary outcome measures.
This has been corrected throughout.

**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:** No conflict of interest.

**Editorial Requests**

1) Please include the date of registration with your trial registration number at the end of your Abstract.

   *This has been done.*

2) Please include the names of all ethical bodies that approved your study in the various centers involved. If you do not wish to list them all in the methods section, please include the list as an additional file and refer to this in the methods section.

   *In the UK approval is required from only one ethical body, which has already been provided in the paper. We are unable to give the governance body as this would remove anonymity for our research site*

3) Please include a list of abbreviations used and their meanings, after your Conclusions.

   *This has been done.*

4) Please include a figure title and legend section after your reference list.

   *This has been done.*