Author's response to reviews

Title: A pilot randomised controlled trial of a Telehealth intervention in patients with Chronic Obstructive Pulmonary Disease

Authors:

Claire L Bentley BSc (c.bentley@sheffield.ac.uk)
Gail A Mountain PhD (g.a.mountain@sheffield.ac.uk)
Jill Thompson PhD (jill.thompson@sheffield.ac.uk)
Deborah A Fitzsimmons PhD (dfitzsi4@uwo.ca)
Kinga Lowrie MSc (k.lowrie@sheffield.ac.uk)
Stuart G Parker MD (stuart.parker@newcastle.ac.uk)
Mark S Hawley Ph.D (mark.hawley@sheffield.ac.uk)

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Author's response to reviews: see over
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Deborah A Fitzsimmons (dfitzsi4@uwo.ca)
Kinga Lowrie (k.lowrie@sheffield.ac.uk)
Stuart G Parker (stuart.parker@newcastle.ac.uk)
Mark S Hawley (mark.hawley@sheffield.ac.uk)

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

**Article:** MS: 1376234401101626 - 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:** 1 **Date:** 15 September 2013

**Reviewer:** Morag Farquhar

**Reviewer’s Report:**

This is largely a clearly written account of what was clearly a challenging study. The paper will have relevance to others implementing, and evaluating, complex interventions beyond Telehealth and COPD and would be a useful addition to the methodological (and empirical) literature. I am not qualified to comment on the cost-effectiveness aspects of this paper, but believe that the remainder of the paper would benefit from the following:

**Major Compulsory Revisions:**

1) Abstract - Methods section: this doesn’t seem to mention the feasibility study methods, only the pilot RCT.

   *The paper has undergone major structural revision so that it reports the results of the pilot study and leaves out the feasibility study. Therefore this revision is no longer relevant.*

2) Abstract - Results section: this section seems to largely report the findings of the pilot RCT in relation to the effectiveness of the intervention, rather than the findings in relation to the conduct of the RCT or the feasibility findings (whereas the conclusion section does refer to these). If looking at this paper as a feasibility study I would be looking for this data in the abstract: the practicalities and acceptability of the methods proposed for evaluating the intervention i.e. the findings in relation to the three feasibility study objectives and the first two pilot RCT objectives (instead most of the results in the abstract relate just to the third pilot RCT objective). I would have liked to have seen included in the results section of the abstract those "identified issues of critical importance for any subsequent full RCT" as referred to in the first paragraph of the discussion section in the main body of the paper.
The paper no longer reports the feasibility study results. However the results section of the Abstract has been modified so that it provides more information on the conduct of the trial (e.g. slow recruitment rate due to reduced staff capacity), and has been structured to follow the specific objectives of the pilot trial.

3) Background, after paragraph four: include some sort of statement of what this study sought to add to the literature given that there has already been a Cochrane review of the intervention (reference 8) - why was this study needed?

The Cochrane review in question was published after this study was initiated. In addition the studies which were included usually delivered Telehealth as part of a more complex package of care, thus it was difficult to separate the effect of the technology from other aspects of the service. This has been clarified within the Background section.

4) Background, Study Context, first paragraph: what were the service referral criteria (as opposed to the inclusion criteria)? These could be given in a box.

These have been included within the Background section under Study Context (see Table 1)

5) Background, Study Context, second paragraph: why was Telehealth introduced? This paragraph just says a decision was made to introduce it, but not why (there is later reference to sustainability, but it should be mentioned earlier).

More information has been included under Background (Study Context) on the reasons for the introduction of Telehealth, i.e. inability to sustain a face to face service in the long term for the (increasing) number of patients in the region

6) Background, Study Context: needs a clearer description of what the Standard Care was like (staffing, frequency of contacts and where) - perhaps in a box? This could have two sections: one for the standard care and one for the intervention?

More information has been included on the Standard Care pathway (under Background, Study Context). Table 2 (formerly Figure 1) already depicts the structure of the two trial pathways.

7) Background, final paragraph: clinician involvement in data collection relating to an intervention they are delivering has the potential to lead to bias, or a change in behaviour by either the clinician or the participant. I was surprised this approach was taken rather than having independent researchers collect the data; I was also unclear why it was taken. Why was it deemed "essential" (as stated in the third objective of the feasibility study in the Research Programme section)? Involving clinicians in generating research questions (so that they have relevance), study design, monitoring, (potentially) analysis of data, and data interpretation is an incredibly helpful and informative approach in applied health services research (ensuring relevance and facilitating adoption of findings), but I am not sure why they were given a role in data collection? Aside from any potential bias (which they themselves seemed concerned about) there was also an impact of using clinicians as data collectors, which is clearly stated in the paper, of considerable amounts of missing data - I would have thought they would simply be too busy and that dedicated research staff would be better placed to do this.
Under the Methods section a paragraph has been added to explain our rationale for involving the clinical team in data collection, e.g. concern expressed by members of the team that receiving multiple visitors whilst recovering from hospitalisation may have been stressful for the participants. Ultimately we tried a different strategy which did not work as well as we had intended, but which we feel provides valuable lessons for anyone who may consider using this strategy in the future.

8) Methods, first full paragraph: who conducted these qualitative interviews and who did the analysis of them?

This is no longer relevant as the feasibility study results will be reported elsewhere.

9) Methods, Pilot Trial, Outcome measurement: need to state how the outcome measures were collected (postal?) and who by, as it only became clear later that clinicians (who were part of the intervention) were meant to be overseeing completion of measurement tools, not just requesting their completion.

Table 2 (formerly Figure 1) has been updated to show how certain outcome measures were collected. As mentioned previously a paragraph explaining clinician involvement in data collection has been included in the Methods section, along with a bullet-pointed list under Data Collection with more detail around how each outcome measure was collected.

10) Methods, Pilot Trial, last paragraph: the last two sentences are results and should be in the results section, not the methods. It would also be incredibly informative to others embarking on similar studies if you included data (or a reflection) on whether the use of the Research Nurse actually helped.

This information has been moved to the Results section, and we have included data (under Results, Objective One) on the improved data collection seen after the introduction of the Research Nurse.

11) Results, Feasibility Study, third paragraph: this paragraph mentions a focus group that is not mentioned in the methods - methods refers only to interviews? Who was in the focus group? All doctors, doctors & nurses? Who facilitated them?

This is no longer relevant as the feasibility study results will be reported elsewhere.

12) Results, Pilot Trial, Trial Methodology, first paragraph, last sentence: I couldn’t work out where the base number 138 came from for the acceptance rate.

This has been made clearer (see Results, Objective One).

13) Results, Pilot Trial, Trial Methodology, second paragraph: a fairly selected group of patients remained after application of the inclusion and exclusion criteria, refusals and other reasons - the impact of this on intervention adoption/roll out could be referred to in the discussion. How well do they represent the patient population?

This is reflected on in the Discussion.
14) Results, Pilot Trial: having worked with lots of COPD patients in a research, rather than clinical, context I am not at all surprised that those on the "Standard Care" arm seemed to benefit from the personal, face-to-face approach which was absent from the intervention arm. Could this not have been identified prior to even the pilot RCT in a non-randomised observational Phase I study?

Our feasibility study did identify this and we have included this particular observation in our Discussion as it is relevant to the pilot RCT findings. However (as is now included in the Background section) the face-to-face model was recognised to be unsustainable in the long term, therefore telehealth was investigated as an alternative to this.

15) Discussion, third paragraph: the loss of the key champion, lack of understanding of data collection requirements by the clinical team and difficulties prioritising research within a clinical remit should ideally be in the abstract. These seem to be crucial points.

Prioritisation of research in the clinical remit is now the concluding comment in the Abstract, and reduced staff capacity is included in the Results part of the Abstract.

16) Figure 1: I needed more detail on this figure. I would list the EQ-5D measurement points (even though it is embedded in the diary, as a reader you forget this detail when you just look at the figure); did the intervention group complete the diaries at 3 days (if not, why not?)?; list the outcomes measured at 8 months; put whether the diary was weekly or monthly for each arm (I was a little confused by this).

Table 2 (formerly Figure 1) has been updated to include more information on the outcome measures, particularly around the EQ-5D and the outcome measurements taken at 8 months.

Minor Essential Revisions:

1) Methods, Pilot Trial, Outcome measurement: "Data" is plural, so "Data were extracted...", not "data was extracted...".

This was a typo and has been corrected.

2) Results, Feasibility Study, third paragraph, second sentence: for clarity change "participants" to "clinicians" or "participating clinicians".

This is no longer relevant as the feasibility study results will be reported elsewhere.

Discretionary Revisions:

1) Background, Study Context, first paragraph: given that the 'standard care' was itself a relatively new intervention, had it been evaluated? Is there any data on whether it was any better than truly standard care (i.e. no discharge service)?

No, the Standard Care service had not been evaluated.
2) Methods, first sentence: could add at "prior to the pilot RCT" to the end of this sentence, for clarity.

   This is no longer relevant as the feasibility study results will be reported elsewhere.

3) Methods, Exclusion Criteria: do you need to list as exclusion criteria items that are the opposite of the inclusion criteria? e.g. no telephone line/unwilling to use Telehealth - are these not covered by the inclusion criteria?

   Have removed ‘unwilling to use Telehealth’ from the exclusion criteria. However we have kept reference to lack of a telephone landline as we recognise this is a barrier for Telehealth services generally.

4) Methods, Exclusion Criteria: were the GPs asked to specify why they identified patients as unsuitable (if they did)?

   No they were not.

5) Methods, Pilot Trial, Outcome measurement: I found the use of "six month follow up" and "eight months after randomisation" confusing - may be better to take a consistent approach to describing data collection timings.

   Terminology regarding timeframes has been carefully revisited throughout the paper. We have attempted to make this terminology more consistent and easier to follow.

6) Methods, Pilot Trial, Outcome measurement: could the self-completed diary tool be included as an appendix (perhaps without the EQ-5D element as that is already available elsewhere)?

   We have not included the diary on this occasion as we wished to avoid attaching an appendix to the article.

7) Methods, Pilot Trial, Outcome measurement: did you do any reliability checks on the diary data against service use database?

   We did not – the main purpose behind the diaries was to try and collect GP visit data, thus we relied on the SUS database for hospital admissions data due to the inherent unreliability of self-report measures. If time and resources had allowed then we would have considered exploring this further.

8) Results, Feasibility Study, third paragraph, second sentence: did they mean "uninterested" or "challenged by"?

   This is no longer relevant as the feasibility study results will be reported elsewhere.
9) Results, Feasibility Study, Agreeing Outcome Measures: it would be helpful to others to include data on how long the SGRQ actually took to complete, if you have that data.

   This is no longer relevant as the feasibility study results will be reported elsewhere.

10) Results, Pilot Trial, Trial Methodology, second paragraph, last sentence: change "the care and research pathway" to "the care pathway and research protocol".

   This has been done

11) Results, Pilot Trial, Trial Methodology, second paragraph, last sentence: was this patient or clinician holidays?

   Patient holidays – this has been made clearer

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: 1 Date: 6 November 2013

Reviewer: Tobias Freund

Reviewer’s Report:

Bentley et al. report on two studies regarding the development and piloting of a telehealth intervention for COPD patients. The topic is of interest for an international readership and the manuscript is well written overall. However, to me this is a classic “two-in-one” paper and I disencourage publication of the feasibility study and the pilot in one paper. I suggest to divide the manuscript into a paper about the feasibilty study (with much more detail on the qualitative results which I miss in the current manuscript) and a paper about the pilot study. Whereas I would encourage to resubmit the manuscript about the pilot to Trials, I suggest to submit the feasibility paper to BMC Research Notes.

One additional remark: I appreciate the decision not to report inferential statistics in this paper. However this should consistently be done (including the economic analysis). If you think the economic analysis is a full study powered sufficiently for inferential statistics, your paper is a “three-in-one”...

The paper has undergone major structural revision so that it now solely reports the results of the pilot RCT. The feasibility study will be reported elsewhere. We have followed the
reviewer’s recommendation to resubmit the pilot RCT manuscript to Trials. We have also removed the inferential statistics from the cost-effectiveness analysis to improve consistency in the paper.

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.