Reviewer's report

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

Version: 2

Date: 1 June 2014

Reviewer: Morag Farquhar

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BMC Trials: Bentley CL et al (01/06/2014)

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):

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).

2) Abstract:

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

b. 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.”

c. 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”.

d. 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.

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

3) Background:

a. Second sentence: “support” should be “supported”

b. 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.
4) Study context:
   a. 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?
   b. 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.

5) The Research programme:
   a. 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.
   b. 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”.
   c. 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...”.

6) Methods:
   a. 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.
   b. Sentence 2: “The pilot followed...” would be better as “The pilot RCT followed...”.
   c. 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).
   d. 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?
   e. 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.
   f. Bullet point 2: I would have thought that Research Nurses would have been cheaper than Specialist Respiratory Nurses?
   g. 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
h. 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”.

i. Outcome measures:
   i. I am not familiar with SUS – can/should this be referenced?
   ii. SGRQ is referred to in abbreviation form before being named in full.
   iii. Bullet point 1 on secondary outcome measures: could describe the diary as “patient-completed diary of GP visits” for clarity.
   iv. Bullet point 2 on secondary outcome measures: EQ-5D needs referencing.

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

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

7) Results:
   a. First sentence feels like a discussion statement/point? Could just start results from second sentence.
   b. Second sentence: suggest insert “clinical” ahead of “staff capacity” – as could suggest capacity problems in the research team too.
   c. Fourth sentence: may be better as “The findings in relation to the three objectives of the pilot RCT are outlined below”
   d. Objective 1 - Recruitment section: delete “extending” in sentence one, as is slightly confusing with the “extended” in sentence two.
   e. Objective 1 - sentence two say how long it was extended by i.e. “…frame being extended from X months to X months”.
   f. 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.
   g. 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.

h. 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.

i. 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…”.

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

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

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

m. 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.

n. 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?

o. 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…”.

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

8) Discussion:

a. “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.

b. 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.

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

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

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

g. 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…”

h. 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.

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

j. 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).

k. Last paragraph, last sentence: confuses complex intervention implementation with complex intervention evaluation?

9) Conclusions:

a. 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…”

b. 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.

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.

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

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.

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)?

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

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

16) Figure 1:

a. Currently labelled as Figure 2, should be Figure 1.
b. The box of excludeds says “Other reasons*”, what does the “*” mean? Typo?

17) General punctuation needs checking:

a. Sometimes “;” is used where “:” would be more appropriate e.g. when listing inclusion/exclusion criteria.
b. A couple of full stops missing e.g. end of paragraph on analysis of primary outcome measures.

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.