Author's response to reviews

Title: The feasibility of a single-blinded fast-track pragmatic randomised controlled trial of a complex intervention for breathlessness in advanced disease.

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Author's response to reviews: see over
Dear Editor

Re: The feasibility of a single-blinded fast-track pragmatic randomised controlled trial of a complex intervention for breathlessness in advanced disease.

Thank you for the very positive reviews of the above paper. The valuable comments of the reviewers have been addressed as follows in the revised manuscript:

1) Reviewer SM discretionary revision: the reviewer asked for clarification on p17 of whether the independent research team’s letterhead included the phrase ‘palliative care’. The revised paragraph now clarifies that the key differences between these two letterhead types was that one was a clinical letterhead, which indicated that BIS was part of the palliative care team (this was the letterhead used by the study at the insistence of the ethics committee) and the other was from an academic institution.

2) Reviewer JH minor essential revision 1: a paragraph has been inserted into the discussion (p21) to draw the readers’ attention to the fact that this feasibility study focused only on patients with non-malignant conditions (and COPD in particular) yet Phase III will include patients with malignancies and the limitations of Phase II in that respect. We did seek funding for a Phase II feasibility study of patients with malignancies but were unsuccessful.

3) Reviewer JH minor essential amendment revision 2: a paragraph has been inserted into the discussion (p19) to clarify the timing of the formal unblinding in relation to qualitative data collection and to give consideration to the potential effects of maintaining blindness on the part of respondents and the potential effects on the respondent-interviewer relationship.

4) Reviewer JH discretionary revision: the suggestion of adding moments of blinding / unblinding to Box 3 was considered and attempted but Box 3 became too complex due to the timing of two of the early unblinding moments i.e. Patient 14’s early unblinding occurred between data collection points (t2-t3; by phone) and Carer 17’s early unblinding occurred at their t1 which was conducted subsequent to their patient’s t1 and randomisation. This data remains available in Table 2, and for Carer 17 has been clarified.

Further to these revisions, a few grammatical errors and a referencing error in relation to the SEIQoL-DW have been corrected which were identified by the authors on revising the manuscript.

Yours sincerely

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