Author's response to reviews

Title: The Person-Based Approach to Optimising the Acceptability and Feasibility of Interventions

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Author's response to reviews: see over
Dear Dr Lancaster

Re: “The Person-Based Approach to Optimising the Acceptability and Feasibility of Interventions.”

Thank you very much for considering the above manuscript for publication in *Pilot and Feasibility Studies* and allowing us to submit a revised version in line with requests from reviewers.

We thank the reviewers for their recommendations and constructive comments. As well as the revised manuscript, we include our responses below.

Yours sincerely

Professor Lucy Yardley
For and on behalf of Ben Ainsworth, Emily Arden-Close and Ingrid Muller

**Reviewer 1:**

1. The first illustrative case study is the least convincing of the three, and does not fully exemplify the first stage of the approach set out in Table 1. It seems to have been largely based on existing evidence and expertise within the research team; there was no formal synthesis of the existing evidence and no qualitative research to elicit user views. The description of the process tails off into a discussion of the difficulty of managing large research teams. This is an issue for any multidisciplinary study, and it is not clear why it should be seen as a particular problem in applying a person-based approach.

*We thank the reviewer for raising this. We have made several changes in line with these comments:*

**P3, para 2:** The first section is only intended to illustrate how guiding principles are formulated, and cannot describe all the other activities that can usefully be undertaken in the first stage of intervention planning. We have added text to clarify that only column 2 of Table 1 represents person-based activities (see also response to point 2).

**P4, para 1:** We now explain at the start of this section that we are illustrating how guiding principles can be formulated from limited evidence at the start of intervention planning, and why this is advantageous.

**P4, para 4/Appendix A:** We now include much more detail regarding our evidence synthesis, including reference to Appendix A (a current working document that lists the sources of relevant evidence).

**P5, para 2/P6, para 1:** We have downplayed references to the Guiding Principles’ role in facilitating work across multi-disciplinary collaborative teams.
2. The status of the approach set out in Table 1 is unclear: are all the activities essential to any person-based approach, or is it a menu that researchers can choose from according to the stage of development of their intervention, state of the existing evidence base, etc? 

_We have clarified (see P4, para 1, and footnote to Table 1) that this is not an exhaustive list, that not all activities will necessarily be undertaken, and that they can be undertaken at different stages._

3. The use of the term ‘feasibility’ is problematic. The three case studies focus on intervention development, which is only one (important) aspect of trial feasibility. Even allowing for the varying use of the terms ‘pilot’ and ‘feasibility study’ in the literature, the case studies are not feasibility studies in any conventional sense. What is meant by feasibility of intervention components is also unclear. In relation to the activity planner (Illustration 3), it seems to refer to the validity of a self-report measure of activity, rather than to the feasibility of implementing the measure.

_We appreciate the need for clarity in our use of the term feasibility, and have therefore added text at the start of the paper (P3, para 1) and our Conclusion (P12, para 1) to explain that the purpose of the work we describe is to maximise feasibility prior to testing it in a formal feasibility study. While we hope that this clarification is helpful in terms of the technical use of the term ‘feasibility study’, we feel that our Illustration 3 does address feasibility in terms of its broader meaning (e.g. operational feasibility), which includes whether an intervention can be successfully used for its intended purpose._

4. The approach described is not really an optimisation process, and might be better termed a way of improving the acceptability of interventions. An optimisation process would involve testing a large number of variants of an intervention, as in the MOST approach, or a long series of development-testing cycles. It is questionable whether optimisation is even relevant to acceptability or feasibility: presumably development would stop once an adequate level was attained?

_It is interesting that this reviewer feels that the term optimization should be reserved for a narrower set of methods of testing intervention variants – although we believe that the term can still be used in its original sense for improving interventions as far as possible, we have replaced it throughout this paper (including in the title) with terms such as ‘enhance’ or ‘improve’._

5. Some details of the methods used in the case studies are unclear: what kind of review was undertaken for Illustration 1? On page 4 the authors simply say ‘we used existing ... literature’ but the conclusions (pp10-11) refer to a literature review. In illustration 3, how was the validity of user reports of physical activity assessed (p9), and how did the researchers know that it improved after the planner was modified?

_Illustration 1: Please see response to point 1._

_Illustration 3: The validity of user reports of physical activity was assessed by the researcher who observed participants filling in the planner while saying all their thoughts out loud; often the context of what they said made it clear that they were misinterpreting instructions or misrepresenting their physical activities. Iterative changes were made to the planner to enable us to observe whether participants were now able to use it correctly. We have clarified this in the manuscript (see P9, para 4)._
It is correct that the person-based approach is designed for interventions that include an element of behaviour change (which most complex interventions do), and so we have now added the term ‘behaviour change’ when first introducing the approach (p3, para 1).

2. In the paragraph starting ‘In this paper’, page 4, it would appropriate to add a sentence to explain why these particular three illustrations were selected for this paper. Based on Table 1, it appears they may have been selected because they illustrate different stages of intervention development and evaluation. If this is the case, this should be stated in the text. The three examples do not exactly correspond to different stages of intervention development, as this is an iterative process, but they do illustrate different ways in which the person-based approach can be usefully applied, and this has now been clarified (see P4, para 2).

3. I wonder if the sentence ‘Overall, the evidence etc’, page 8, could be expanded so the authors explain in what ways they think qualitative research is an essential tool in improving the acceptability of an intervention. I know the preceding text has demonstrated this, but I feel it would benefit the reader to explain whether they think it is the open, flexible nature of qualitative methods (allowing participants to raise issues that are salient to them and perhaps not previously considered by the researchers) and/or the fact that qualitative methods encourage a iterative approach to intervention development. Illustration 2 suggests both, so it might be worth reinforcing this. We thank the reviewer for this suggestion. Because quantitative approaches can be used iteratively (e.g. in quantitative optimization approaches) we believe that it is the first advantage that is unique to qualitative methods, and have therefore added a sentence to this effect in the final paragraph of Illustration 2 (see P9, para 1).

4. As the authors have talked about think aloud interviews within Illustration 2, on page 9 they might want to explain (rather than simply reference), what is meant by observational think-aloud interviews. P9, para 4: The methods used in both illustrations were the same (hence use the same reference), and so we have removed the term ‘observational’ which seemed to imply a different method, but remind the reader that observing people helps the researcher to understand their problems using the intervention.

5. On page 9, the authors explain that a decision was made to remove ‘climbing stairs’ from the physical activity planner. This was clearly the right decision but often in intervention development, participants’ accounts suggest they may struggle with specific aspects of an intervention. The research team then have the challenge of deciding whether or not it should be dropped (which could lead to insights/measurements being lost), altered or replaced. The authors might want to comment within the Discussion section that such ‘tensions’ can exist and how researchers should address them. Thank you for this comment, we now acknowledge this in the discussion (P11, para 2) as follows: “These illustrations also highlight the potentially difficult decisions research teams have to make when modifying interventions. Sometimes decisions can be made on the basis of intervention planning and the guiding principles. Another way we address this is by making iterative changes and assessing the impact of those changes with further qualitative interviews.”

6. Reviewer 2 referenced a number of minor grammatical/wording changes. We apologise for this, and have made several changes throughout the manuscript (not numbered).