Author’s response to reviews

Title: Learning from patient involvement in a clinical study analyzing PET/CT in women with advanced breast cancer

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Author’s response to reviews:

Response to reviewers

Thank you for reviewing our manuscript. According to the reviewers’ comments, we have made substantial revisions in order to improve the manuscript. We hope these revisions may allow the manuscript to be published in Research Involvement and Engagement.

Reviewer 1

Thank you for reviewing our manuscript. We have given further consideration to your comments and advice as follows:

1. I’m certain that if you had worked with patients with a different personality type or approach to collaboration, that you would have had a very different outcome. I don’t feel that you touched on this at all and as a consequence, a crucial part of the overall picture is missing.

Response:

We elaborated more on the invited patients in the method section and discussed on the personality type and the impact on our results. It is true, that involvement of more fragile women or women from the daily clinic might have resulted in a different outcome. We have touched upon that in the revised manuscript.
2. It would be good to know what characteristics you would chose of patient representatives in future studies so that it will help others to achieve the same positive outcomes as you did.

Response:
We have characterized future patient representatives in the perspective section.

Reviewer 2

Thanks you for the very important points. We agree that it should be clearer that our paper should encourage clinicians to involve patients as partners in future research projects of true interest and potential outcome.

3. The primary concern is that this is presented as an evaluation study. It would be more accurate to present this as a 'reflective case study' or 'descriptive report'.

Response:
We agree and have revised the method section, and report the study as a descriptive study. Further, we have revised the title; “Learning from patient involvement in a clinical study analyzing PET/CT in women with advanced breast cancer”

4. The piece is based on the team's internal observations of their public involvement experience

Response:
The report is based on our own experiences of attitude as well as an observation of other researchers’ attitudes. These “other” researchers are not authors of this manuscript. We have made more effort in describing the change of attitude in the manuscript.

5. p.4 line 73 and 76

Response:
We have revised the background section
6. p.5 line 119 and p.9 line 203-217

Response:

The text has been revised by a native English person.

Reviewer 3

7. There are some statements in the introduction that are not entirely supported by the literature. For example, the finding that the impact of PPI is greatest if partners have lived experience was related to a specific set of outcomes (recruitment) and may not reflect other aspects more broadly. Also, there is a focus on the effects of PPI in quantitative research, particularly in the US. One recently article is Forsythe, Carman et al 2019 describing influence of engagement in PCORI studies, and there are others that should be included.

8. It's not clear what the authors mean in the second paragraph - in what ways are attitudes more positive? Changes to what kinds of practice?

Response:

Thank you for your comments. We have revised the background section.

9. An accurate description of the study is needed in the first sentence of the Methods. The current study is not "clinical" observational. Also, please clearly state it's comparing experiences with an ongoing clinical study to a previous one.

Response:

We agree and have revised the method section, and report the study as a descriptive. Further, we have revised the title; “Learning from patient involvement in a clinical study analyzing PET/CT in women with advanced breast cancer”
10. More needs to be done throughout the paper to demonstrate that these two studies are comparable. While they both deal with breast cancer patients, it seems that there are meaningful differences in the types of patients, the intervention delivered, and the amount of time for study participants (2 scans per day vs. something less intensive). These differences may account for differences in recruitment across studies.

Response:

Thank you for this request. We have made more effort in describing the ongoing study into more details, since more complex parts in the study design (regarding blood test for genomic mutations) was not described. It was complex information regarding genomic mutation analysis for which the patients before enrollment had to decide the level of information they wanted in case of detection of a genomic inherited mutation. We believe this element to be substantial in the comparison of the two studies.

ClinicalTrials.gov NCT numbers have been added for both studies to visualize the need for a 10-month extension in the previous study. The ongoing study has recruited more than expected in due time.

11. It's not clear why the authors only compare the first year of recruitment. The differences could be better assessed upon completion of recruitment for both studies.

Response:

Since data regarding of total inclusion period is now available regarding the ongoing study, we have updated the results. As mentioned above the previous study was extended for 10 month of what was planned in order to recruit 67% of expected number, whereas the ongoing study recruited more than expected in due time.

12. Throughout the paper, the authors should more carefully describe that recruitment was more successful in the study with PPI but causal language is not warranted given the methods used in this paper.

Response:

We have revised misleading phrases with causal language.
13. The authors should be clear that they didn't "observe" researcher attitudes- they are describing their own attitudes. Also, much more detail and depth is needed about the changes in their attitudes.

Response:

The report is based on our own experiences of attitude as well as an observation of other researchers’ attitudes. These “other” researchers are not authors of this manuscript. We have now described this part in the manuscript.

14. The influence on partners on analyses and dissemination will also be much stronger when more of the research study is completed.

Response:

We do agree. However, the study results will be available at earliest in end 2021.

Reviewer 4

15. It is important to ensure that PPI is involved in all research from the outset to make it more relevant to those for which the research is focussed. Please see Patient and public involvement in health literacy interventions: a mapping review, Howard Wilsher et al 2017, which gives detailed information about how PPI was used and the effect on outcomes. The authors may wish to read and reference this.

16. Page 4 - Perhaps add something about early PPI is preferable - see study above.

Response:

Thank you for your suggestion. We agree, and have included the reference in the introduction section.

17. The language needs to be checked throughout the document. There are issues with the tense used and putting together of sentences.

18. Page 4 Line 93 - sentence needs revision as per general comments above about language.

20. Line 107 - change have been to were

21. Page 6 Line 134 - what do you mean by defined qualifications?

22. Line 135 - change to acknowledgment

23. Page 13 Line 297 - change "disgraced"

Response:

The manuscript has now been revised by a native English person, who has been mentioned in the acknowledging section.

1. Page 3 Line 54 and all other instances - remove "representative Page 3 Lines 61-64 - these sentences should be refined and made more user friendly. Eg. line 60, change to "In previous research fewer patients....."

Response:

Patient partner has been used more frequent throughout the manuscript.

2. Page 7 and 12- Funding activities - is this necessary?

Response:

We want to turn the researchers’ attention to the fact that a “positive” side effect of “serious” involvement of patients as partners is now a requirement also outside the anglosaxon world. We have revised the manuscript into major outcomes and additional outcomes.
3. p.5 line 113:

Response:

Since the previous study only enrolled patients previously treated for local breast cancer and not current breast cancer, we find it misleading to erase the word “previously” in this sentence. We have revised the sentence.

4. Page 9 - would be nice to have a PPI quote too.

Response:

Thank you. We have included a PPI quote regarding the written information material as suggested.

5. Line 313 - Perhaps the materials developed by PPI made a difference to recruitment?

Page 14 Line 324 - PPI was involved in materials development not study design?

Would recruitment have been greater if PPI had helped the research recruit?

Response:

We will definitely try this in future studies, and we have included these ideas in the perspective.

6. I do not think that Table 1 is necessary.

I do not think figure 1 is necessary or should have the inclusion of when PPI started.

Response:

Thank you for this comment. We have chosen to keep the table and figure for a quick overview for the reader. We have revised the figure.