Author’s response to reviews

Title: “PROUD to have been involved”: An evaluation of participant and community involvement in the PROUD HIV prevention trial.

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Author’s response to reviews:

We thank the reviewers for their helpful comments. We have made a number of changes to our manuscript in response to the points they raised, as detailed below. We believe this has improved the paper, so hope you will now consider it for publication.

REVIEWER 1

1. It suggests that the work is qualitative, but there is no evidence of qualitative methodology beyond some free text questions in a survey and researchers finding themes in the data.

*The study itself was not qualitative, but rather involved the completion of closed and open questions on a survey. However, we qualitatively analysed the free text responses on the survey to identify themes. This is a common approach to the analysis of free text data even when collected as open survey questions.
2. Findings do not advance knowledge of PPI.

*This article provides an evaluation of PPI within a single study that involved 99 trial participants and community members through a diverse range of approaches. The evaluation is based on responses from 46 involved participants, eight involved community members, and six researchers. We are unaware of other published evaluations of PPI in a single study of such a scale. We hope that by publishing this evaluation we will encourage other researchers to be more ambitious in terms of the extent and range of PPI employed within their studies.

We note that Reviewers 2 and 4 categorised it as an article of importance in its field, and Reviewer 3 as an article whose findings are important to those with closely related research interests.

REVIEWER 2

1. It would be useful to ensure that all acronyms are defined the first time even though there is a list of abbreviations.

* We have made this change.

2. Page 6 - line 51 - Is the reason the survey questions were not reviewed by public involvement contributors because they were validated and therefore could not be changed following feedback? If this is the case, perhaps it would be helpful to explain this.

* The survey questions were not validated.

3. Page 6 - line 51 - "We carried out two structured surveys" - it would be good to say that the surveys were for the purpose of the evaluation for clarity

* We have made this change.

4. Until you get to page 5, it is not clear what PPI was undertaken throughout the study apart from the these references: (Page 5 - line 52 - there is reference to an e-group and involvement of community representatives on management committees (page 6 - line 2). Although there is a list of activities in Box 1 - this is not detailed. On page 15 there is reference to study participants being involved in study documentation, recruitment strategy and dissemination however this wasn't well described in the Background section and I think setting out what involvement took place there would be useful context.
As the PPI activities carried out in PROUD have already been documented and published, we did not want to duplicate that here. But we recognise that it is important to understand what PPI activities there were within PROUD when reading this article. We have added further details to Box 1 to address this, along with information on the e-group.

5. Page 10, line 1 - why would a PPI survey have a depression element to it?

*We used a PPI approach to assess the credibility of our interpretations of study findings showing changing levels of self-reported depression during the study. We have added information about this.

6. Page 10 - line 56 - it might be useful to explain why "We did not ask researchers for their main reasons for implementing PPI activities."

* We have added information about this.

7. Page 14 - line 1 - it might be useful to explain why "We did not ask researchers about their personal experience of the PPI activities."

* We have added information about this.

8. Page 19 - line 56 - it might be useful to explain why "We did not ask researchers about the impact of PPI on them personally,"

* We have added information about this.

9. Page 22 - it is hard to understand what is being described by the quote at the bottom of this page and may need a clear description prior to the quote.

* We have tried to clarify this above the quote.

10. Page 24, line 27 - can an amount be stated for "minimal resources" in order to evidence to other researchers that PPI can be done with "minimal resources"
* Unfortunately, we did not document resources used for PPI in this study. There was no explicit budget line for PPI within the study. It is an important consideration and we have added this to the discussion as a recommendation for future PPI evaluations.

11. Page 25 - para starting at line 9 - it would have been interesting to include the possible reasons why study participants haven't been or aren't routinely included in public involvement activities in the study in which they are participating i.e. the concern over bias/ the idea that it wasn't considered to be appropriate.

* We have added this.

REVIEWER 3

1. It is a shame that some of the PPI participants were not asked to contribute to writing the paper as co-authors.

* All survey respondents were asked at the end of the survey if they wanted to be co-authors on this paper, and several took up this offer. We had not made this explicit to protect their privacy. We have added a note in the Authors’ contributions section to clarify this.

2. The researchers should consider inviting a lay PPI person to be part of their funding submission team to be involved in all aspects of the research as and equal up to and including co-authoring any papers as well as the research report. This is a major omission in this research and is a requirement of some funding bodies which could be mentioned in the paper.

* This is a really important point. The PROUD study was not actually funded through a grant but rather through internal MRC and PHE funds, so there was no opportunity for community members to be ‘co-applicants’. However, it is still a relevant issue and we have added a note to this effect to the discussion. Community members were involved in the design of the PROUD trial.

As noted above, participants and community members involved in PPI were invited as co-authors on this paper.
3. A major omission in the paper is a statement of the % of total cost and time of the project to PPI activities and how this was split across the various parts of the study. This should be used to enhance the discussion section as well as the conclusions, especially lines begging 455, 259, 543, 523.

* This is a valid point. PROUD was not funded by a research grant (rejected by NIHR) and therefore was funded internally by MRC-CTU and PHE and as such we did not have a formal PPI budget line. The PPI activities were coordinated by the trial social scientist, meeting rooms for the events were usually cost-free, and PPI members were not reimbursed. As such it is not possible to cost the PPI activities. We have added the need to cost PPI activities in future trials in the discussion.

4. Even though a list of abbreviations is given, they should be defined in full when first used.

* We have made this change.

5. The methodology is satisfactory, though it should be stated the amount of lay representation used in the study design.

* If this refers to PPI in the design of the PROUD trial, we have added further details to Box 1.

PPI in the design of this evaluation was limited to the patient/community members who are part of the MRC CTU at UCL PPI group reviewing and developing the plans, as described in the methods section.

6. It would add to the paper is the reasons why the community suggestions were not acted upon could be discussed.

* In this paper we recommend ‘real time’ evaluation of PPI activities in future trials. We have actually implemented a real time evaluation in a subsequent trial that specifically aims to capture various of opinions on specific topics and note when and why community suggestions are or are not taken forward. Unfortunately, we did not conduct real time evaluation in PROUD and therefore are unable to provide this detail. We hope to evaluate the real time approach shortly. We have added a note about the need to capture this to the discussion. Much of the PPI was designed to inform a future trial, that, in the end, was not needed due to the success of the PROUD study.
7. Data relating to the metropolitan non metropolitan split should be included as well as a
detailed discussion of the issues it raised in relation to PPI.

* Box 1 provides details of where activities took place. Table 1 gives the breakdown of
participant and community respondents to the survey by location (Greater London vs rest of the
country). We do not have further details about the location of respondents.

We have added a sentence to the discussion section on the need for resources to support PPI
activity in a wider range of geographical settings.

8. The recommendations should be split into requirements and suggestions and discussed in more
deepth.

* Thank you for this suggestion. However, our aim was to evaluate and report the PPI approach
used in PROUD. Although we hope that reporting our findings will be useful to others
considering different models of PPI, including participant involvement, we do not feel we are in
a position, based on this single evaluation, to specify requirements for other studies. Instead, we
prefer to leave it up to readers to decide which of the recommendations are relevant to the
context of their study. Guidance is available to researchers from various sources, including
INVOLVE and Good Participatory Practice guidelines, and we have included references to these.

REVIEWER 4

1. The use of the PreP and PPI acronyms in the plain English summary needs explaining

* We have made this change

2. Line 107: I question whether the INVOLVE definition of patient and public involvement
entirely fits here, particularly with the involvement of research participants. In this case, its
'Research being carried with and by research participants as well as about 'about' them - not
'rather than'

* We have used the INVOLVE definition of PPI as this is the most commonly used definition of
PPI in research in the NHS (where this study was conducted). We feel this definition captures
both the participant and community involvement aspects of PPI within the study. (Even though
the INVOLVE guidance advises against involving participants, their definition does not exclude
the potential of it.)
3. Line 108: 'Participant' and public involvement is a new phrase, and perhaps should not be used with the acronym PPI, which is more recognised as patient and public involvement

* We have amended this.

4. Line 117:127 - the challenges of involving people with lived experience 'representing' the study population and the reason for involving trial participants seem reasonable. Though the same challenges are relevant for involving other 'hard-to-reach'/seldom-heard'/underrepresented group in research. What efforts were made to identify people to be public contributors (who were not trial participants) in the first instance?

* We did not seek individual members of the public to participate in PPI activities. We planned from the beginning to involve members of community organisations and study participants.

5. While Box 1 outlines the public involvement activities in the study, the manuscript text doesn't really describe the nature of these activities, i.e. whether they were face-to-face, teleconference, videoconference etc. Line 112 also mentions an 'e-group'. It's not explained what this is, nor whether these were part of the public involvement activities in Box 1.

* We have added the e-group to Box 1, and added some further details to the text about the use of both face-to-face and teleconference meetings.

6. Further information on the public involvement activities is needed to enable the reader to better understand how public members were involved in the study. In total 99 people were took part in public involvement activities. This is a huge amount in comparison to the studies, compared to the 'normal' amount. For example in Box 1, further detail is required on the specific activities and contribution of the public contributors to the committee and groups in Row 1. Also the frequency of meetings would be helpful. For example, did the advisory committee meet once or were there several meetings throughout the study? How many people were involved in each? Studies involve public members in these groups to a different extent and purposes, so understanding the role of public contributors in these groups for this study would be helpful.

* We have added further information to box 1 on how many community representatives were involved in the groups listed in (what was row 1 of) the box, the role of the groups, the frequency of meetings and the areas of the PiiAF framework which that involvement activity had impact on.

We have added information on the coordination of these activities.
7. Given the large numbers of people involved, it would also be helpful to the reader to understand how this activity was coordinated and how people were supported.

* PPI activities were coordinated by the trial social scientist, with some participant involvement activities facilitated by members of the Community Engagement Group. We have added this information to the introduction.

8. The authors have explained the role of the MRC CTU’s Group in the developing the evaluation study in broad terms. But how were public contributors involved and what contribution did they make? Was there any learning gained from this involvement? Was their involvement limited to the pre-study period or were they involved later in the study, e.g. analysis/interpretation of the data, developing this manuscript

* The MRC CTU at UCL’s PPI Group’s involvement was limited to the development of the PPI evaluation survey. However, they were also instrumental in encouraging us to persevere with writing it up for publication – without them we may never have finished this.

We did not seek further PPI in the development of the PPI evaluation survey.

9. Lines 160-162: Typically REC approval is not required for public involvement activities in research (though some activities do require ethical approval); this is an area which is often misunderstood by the research community. I appreciate that the involvement of research participants might necessitate ethical approval, so perhaps its worth commenting on this in the manuscript. Also the research on the public involvement would require REC approval, so please clarify whether REC approval mentioned was for the PROUD study only, or was this for the evaluation study?

* We have added a comment on this in the manuscript, and clarified what the ethics approval was for.

10. It seems from Box 1 that several of the involvement activities took place before the study and recruitment has started. So how many of the trial participants involved in the study were in the intervention group and how many were in the control group once the study started? Did this influence how they were involved and their responses to the survey?

* No participants were involved in involvement activities that took place prior to the start of the trial. These activities only involved community members.
We did not collect data on the randomised arm of participants who took part in involvement activities, nor those who responded to the survey.

11. Related to point 9, the influence of trial participants being involved in the design of studies on the potential for introducing bias in a randomised control trial need discussing. For example, what are the implications of future trial participants knowing about study endpoints and outcomes, as well as potentially having a sense of ownership or buy-in to the study and wanting it to succeed, on how their responses to self-reported outcomes collected in the study might be influenced?

* We discuss this issue more fully in our previous paper(1) where we argue that participant involvement can, by its nature, only take place once a trial has started enrolling participants. While community representatives involved in the design of trials may go on to become participants, we do not consider their involvement in the design to have been participant involvement. Study endpoints and outcomes are usually detailed in patient information sheets, so, in theory, all participants should have some knowledge of them. Similarly, participants who have not been actively involved in a study may have strong buy-in and want a study to ‘succeed’, so the issues are not necessarily limited to actively involved participants. The one aspect of PPI where we considered the risk of bias to be too great to involve participants is DSMCs.

12. The specific contribution and impact of public involvement to the study is rather vague (though there some things are mentioned in the quotes). It might be helpful for the reader by providing a box summarising the key impacts of public involvement on the study and to the people (and researchers) involved.

* We have added the domains (based on the PiiAF framework) where PPI activity had an impact on the trial to Box 1.

REFERENCE: