Reviewer’s report

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

Version: 0 Date: 20 Feb 2020

Reviewer: Steven Blackburn

Reviewer's report:

Thank you for this opportunity to review this manuscript.

In my opinion, this is an important article both in terms of the generating knowledge for the advancement of public involvement in research, but also due to the contribution of public involvement to an important research study.

Overall, the manuscript is well structured, written and balanced, given the limitations in the study design - a survey conducted several months after the trial concluded. Issues that the authors have acknowledged.

The following points are made with a view at strengthening the manuscript:

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

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'

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
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?

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.

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. 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.

7. 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
8. 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?

9. 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?

10. 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?

11. 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.

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