Author’s response to reviews

Title: Value and learning from carer involvement in a cluster randomised controlled trial and process evaluation - Organising Support for Carers of Stroke Survivors (OSCARSS)

Authors:

Claire Mitchell (claire.mitchell@manchester.ac.uk)
Kelly Burke (kellyburke531@msn.com)
Natalie Halford (nat71985@hotmail.co.uk)
Katy Rothwell (katy.rothwell@stroke.org.uk)
Sarah Darley (sarah.darley@manchester.ac.uk)
Kate Woodward-Nutt (kate.woodward-nutt@manchester.ac.uk)
Audrey Bowen (audrey.bowen@manchester.ac.uk)
Emma Patchwood (emma.patchwood@manchester.ac.uk)

Version: 1 Date: 02 Apr 2020

Author’s response to reviews:

Sophie Staniszewska and Richard Stephens
Editors in Chief
Research Involvement and Engagement
April 2nd 2020

Dear Editors,

Subject: Your submission to Research Involvement and Engagement - RIAE-D-20-00004

RIAE-D-20-00004

Value and learning from carer involvement in a cluster randomised controlled trial and process evaluation - Organising Support for Carers of Stroke Survivors (OSCARSS) Claire Mitchell; Kelly Burke; Natalie Halford; Katy Rothwell; Sarah Darley; Kate Woodward-Nutt; Audrey Bowen; Emma Patchwood Research Involvement and Engagement

Please find below my response to the reviewers. I have highlighted text and cross through where I have made changes to the manuscript.
Reviewer #1: This is a well written paper that I enjoyed reading. It is an important paper for as the authors rightly say, there are currently few articles that report the involvement of users and carer in RCTs, particularly the involvement of carers. So this article will be extremely useful for research teams and their research user groups regarding how to document and report the process of involvement in RCTs.

Response: Thanks for your helpful comments and suggestions to improve this paper.

1) Ethics - I acknowledge that Involvement in research does not require research ethics approval, as the authors state in at the end of the article in the ethical approval section. However, the evaluation of the PCPI reported in this article does read very much like a piece of research to me, with verbatim recording of discussions/interviews, thematic data analysis and reporting using quotations from the interviews (p7-8). I therefore wonder whether this evaluation was covered by the wider ethical approval for the main study? Or whether the research team consulted with an ethics committee who said that ethical approval was not required for this evaluation? I feel that as a reader, this information is missing. Or if the authors are clear that ethical approval was not required for the method of evaluation undertaken, then a brief justification of this would be useful.

Response: Thank you for raising this important point. We were keen to make it clear in this paper that this was not a piece of research. However, we appreciate that the participants recording, informal qualitative analysis and anonymised quotes have raised concerns in this area. The interviews with our PCPI colleagues were recorded with participant consent as part of ethical approval for a broader study of co-production. This ethics approval is now specified in the paper. The signed consent form specifies that the data collected in this broader study may be used in future studies by the same research team. We appreciate the importance of demonstrating clear ethical consideration and hope this now satisfies the reviewers. This addition is now highlighted in the section: Ethical approval and consent to participate.

2) In this article you report both the benefits and challenges of the process of involvement, as has been reported in previous accounts of PPI in studies. This discussion is really interesting and useful. However, at the moment the abstract just reports on the positive aspects of involvement and not any challenges. I think the abstract and plain English summary should have a sentence or two regarding the challenges, such as the time commitment and emotional aspects of involvement, as reported in the article. This will provide a more balanced account of the findings for readers who sometimes just read the abstract in the first instance.

Response: Yes thanks for highlighting this, it was important for us to offer that balanced account so we have added this to both the plain English summary and abstract. We have made some minor wording changes, highlighted, to keep the word count to the correct number.

Reviewer #2: I liked this submission because 1) it makes clear that it is about method for what makes PCPI work - valuable info for others in the field including me 2) it uses the phrase 'added value': this is really important because, in my experience, if PCPI does not improve a research project, why have it? Put another way, my experience is that public contributors would be better
spent opting out of projects that fall below the standards described in this submission 3) it includes the word 'Carer' in the acronym PCPI; It is my experience reference to Carers is lamentable - lip service if you like, despite my trying to change this - and this is at high level in health and social care research: I am not in favour of new acronyms but here it is welcome and justified. 4) the term 'added value' does beg the question of what this means: it is tempting to want to express this in numerical terms - e.g. Lykert scale but, rather reluctantly, I don't think we are at that stage; also added value may not be apparent until some time in the future (e.g. choosing the best school for a child). Here added value is described as text and I think this is honest and best; we are still at an early stage of public in health research, this is likely to develop with experience but for the moment the textual description is justifiable and appropriate 5) the very positive interaction between academics and public is welcome and to be applauded - my experience is that this can be rare even by highly respected senior academics: this submission will be a great value to such people; I do hope that it will help set the standard for younger health research academics. 6) the submission is not about outcome measures for the project: the move by Universities to judge academic value by measurable outcome measures is, in my opinion, flawed and can count against the career trajectory of researchers who are doing valuable work. Universities should not judge research solely on financial terms? 

Summarising, I thank the authors for a valuable and enjoyable read.

Response: Thanks for your kind comments and again they offer us such a helpful insight into this evolving area and what is meaningful to public contributors involved in health research.

Reviewer #3: I very much enjoyed reading this paper and congratulate the authors on a clearly written engaging account of the PCPI in the OSCARSS study. The conclusions they draw relate clearly to the results and the work is, as they suggest, a useful example in encouraging other health researchers to engage enthusiastically in PCPI, as well as providing useful recommendations about what facilitates engagement and contributes to success.

I suggest a couple of minor revisions:

1. The description of the analysis is currently very thin. It would benefit from a little more detail about the process between initial coding and arriving at final themes.

Response: Thanks for your comments and for your suggestions to improve this paper. We have now offered greater clarity around our initial coding and themes in the Data and Analysis section.

2. I would like an explanation of the identifying letter and number at the end of each quote.

Response: Thanks, we have now explained our system of how we identified each respondent quote by anonymous code.

Co-Editors-In-Chef:

We have classed this as a "Major" Review because the ethics issue is a fundamental point, and not because the paper as a whole needs significant rewriting. Having said that however, the reviewers raise salient points about the thinness of the analysis section and the absence of an evaluation of challenges or difficulties - which perhaps were overcome?
Response: We understand the query around ethics, as above, and have clarified that ethical approval and informed consent was secured with the ethical approval number now included in the relevant section.

Analysis: We did not offer enough information around analysis and have now included more detail in this section.

Challenges: We have now offered more evaluation of the challenges in the discussion section. We have tried to explain that these were not necessarily overcome but really an acceptance that working with a wider group of people all with different backgrounds would inevitably pose more challenges but the benefits would outweigh this.

Yours sincerely,

Dr Claire Mitchell, Research Fellow &amp; Senior Clinical Lecturer, Ellen Wilkinson Building, Oxford Road, University of Manchester, Manchester M13 9PL, t: +44(0)1612753442, e: Claire.mitchell@manchester.ac.uk