Author’s response to reviews

Title: "We all want to succeed, but we've also got to be realistic about what is happening": An ethnographic study of relationships in trial oversight and their impact

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Author’s response to reviews:

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Dear Editors,

Re: TRLS-D-17-00569

"We all want to succeed, but we've also got to be realistic about what is happening": An ethnographic study of relationships in trial oversight and their impact
Thank you for sending the reviewers’ comments on the above manuscript submitted to Trials. We have amended the paper in response, highlighting our changes, and believe the paper to be strengthened as a result. Point by point responses to the comments are given below.

Please note that Anne Daykin and I are joint first authors, and Alison Shaw and Athene Lane joint last authors on this paper. Your submission system does not have a way of indicating this.

We look forward to hearing from you in due course.

Best wishes,

Lucy Selman

Reviewer #1

1 Thank you for the opportunity to review this very interesting paper. From my personal experience, the findings seemed very familiar and well worth highlighting to the general trial audience who may otherwise easily accept some of the more negative reported dynamics as custom and practice.

Thank you

2 I was particularly pleased to see the COREQ reporting guidelines checkbox completed, which makes my job a lot easier and demonstrates the overall rigour of this article.

Thank you
3 However, the entry for Methodological orientation and Theory referred to an unreferenced paper, which needs expanding within the manuscript.

We have added a sentence to the paper on our orientation on page 5 and updated the COREQ table, removing reference to our previous paper.

4 It took me a while to figure out the sample selection. There are eight trials but there are five groups of interviews and 51 interviewees. As a qualitative research study, data collection and analysis relies on homogeneous groups, with each representing a perspective. The authors acknowledge this in lines 54 to 56 but that doesn't seem to follow through to the allocation of groups, which seems mixed - what are the defining criteria of the interviewed groups?

We interviewed people involved in trial oversight and/or conduct who were likely to have insight into how trial oversight decisions are made between oversight groups, i.e. ‘information-rich cases’ (Patton, M (1990) Qualitative evaluation and research methods pp. 168-186).

Within this group, which was unified by their experience, we sought to sample purposively to ensure variation in the sample by trial topic/population, type of oversight group (TMG/TSC) and role within the group (statistician, Chair etc.). This approach is commonly used in qualitative research to help ensure representativeness (and we question the notion that qualitative research relies on homogeneous groups – see e.g. Patton (1990), ibid). As described in the text (page 6), we also interviewed additional people involved in trial oversight. To ensure transparency, we present details of all participants in Table 1. We have added further explanation of sampling on page 5 for clarity.

5 It was refreshing to see fieldnotes being used appropriately and referenced throughout the paper, so often there is a mention of them with regard to data collection but these are not referenced in the results.

Thank you
6 In terms of the standardised observation schedule, it would be interesting to know how that was developed and whether it took account of non-verbal language as well.

We have added details of its development (page 6) and a summary of the observation schedule in the new Box 1.

7 The authors have paid careful attention to research rigour and have co-coded a subset of interviews transcripts, it would be useful to reference the percentage of the full set.

AD coded all the data. All the interview and observational data from 4 of the RCTs were also independently coded by another researcher (AS, SM, GS or HC). Identified minor differences were discussed by the team, resolved and integrated into the analysis. We now state this on page 7.

8 I'm not sure about the word triangulation is applicable here, I'm more used to hearing that in relation to multimethods research, to enhance convergance. I understand what the authors mean and maybe reference to cross case/sample analysis is a better phrase to use.

Methodological triangulation does not refer only to the use of quantitative and qualitative techniques to identify and explore convergence/divergence. It refers to any use of different types of methods to help provided more comprehensive insights into the phenomenon under study (see e.g. Reeves et al. Qualitative research methodologies: ethnography, BMJ 2008). We have added reference to this paper (page 7) for readers who wish to know more about the technique.

9 There is a good spread of data from the various trials and the various professionals but I feel there is that little attention paid to PPI representation, who are integral members of trials teams at all levels. I would have thought PPI reps should have sat within all five of the interview groups. It would certainly be good to see an extract from the PPI representative in the paper.

We completely agree with the importance of PPI and are currently finalising a paper dedicated to the role of PPI in trials from this study. To better represent PPI in the current paper we have added reference to another PPI interview which we had previously included only in our paper on
PPI (Table 1). This correction now gives the total number of interviews conducted, 3 of which were with PPI members. We have also added a quote from a PPI representative and cross referenced to this aspect being reported elsewhere (page 8 and 23).

10 I think the most powerful theme is the Communication theme, which is the root cause of issues across many different topics, but I was particularly taken with Page 16 and the key question about overall responsibility, with its divergent and very telling responses. I felt that this could have come through far more strongly in the recommendations.

Thank you. We agree that the importance of good communication and the key question of overall responsibility are central findings and have emphasised these more in the strengthened Recommendations (Box 4).

11 The intelligent discussion leads to a box of recommendations regarding trial oversight, these feel quite tentative in parts and, given the data, I think that there is an opportunity to emphasise the issues in a stronger way and maybe consider taking wider consultation on an eventual definitive set of recommendations for increased impact.

Thank you for this suggestion. We have strengthened the recommendations as suggested (Box 4). In doing so, we have combined certain recommendations, and restructured the recommendations, with mention in the Discussion that they are proposed for wider consultation (page 22). Findings from this study, along with findings from a parallel quantitative study (by Gamble et al.) are being used to inform updates to the terms of reference for TSCs.

12 The authors have been careful to retain the anonymity of the participants but it might be worth checking the use of gender throughout the manuscript so that he/she is used consistently in preference to single gender references.

We have not retained gender anonymity for respondents – these are reported in Table 1. However, for clarity I have changed our use of ‘he or she was’ to ‘CIs were’ on page 17, as this was referring to all CIs in general, not to a specific person.
13 Overall, congratulations to the authors on a very good paper, which will be of interest to a wide audience, and has the potential for high impact by the promotion of the resulting recommendations.

Thank you

14 Finally, outwith this paper, it may be worthwhile to collaborate with http://www.trialforge.org whose position paper has been published in Trials https://trialsjournal.biomedcentral.com/articles/10.1186/1745-6215-16-S2-P231.

Thank you for this suggestion, which we will follow up.

Reviewer #2

1 This is an interesting article on how the relationships between the stakeholders affect the trial oversight process.

Thank you

2 My main comment lies around the concept of 'ethnography' and the risk of overusing it. It is difficult to see in which ways this 'ethnographic' study differs from an 'ordinary' qualitative study and what the added-value is. Therefore, the manuscript would benefit from more justification for choosing to carry out an ethnographic study and what the added-value of such a methodology is.

We frame the study as ‘ethnographic’ due to the use of extensive participant observation as well as interviewing. While the study did not involve as prolonged exposure in the field as an anthropological ethnography, its methods are similar to other health services research studies which are classified as ‘ethnographic’ (e.g. Coiera, E (1998). Communication behaviours in a hospital setting: an observational study. BMJ; Ware et al. (1999) An Ethnographic Study of the
Meaning of Continuity of Care in Mental Health Services. Psychiatric Services), and we follow methods outlined in Reeves’ discussion of ethnography in the BMJ (now referenced). We have added justification of our approach and further details of its added value on page 5. We also believe the inclusion of the new Box 1 outlining the observation schedule clarifies our methodology.

3 In addition, it would benefit from having more detail on the advantages/inconveniences of the ethnographic methods used, in particular the observations: were they overt/covert and what were the reasons for it?

The observations were overt, enabling the researcher to take detailed concurrent notes on the meetings attended (see Box 1) and follow these up for further discussion in subsequent interviews. We have now stated this on page 5. We have also added some reflections on the strengths and limitations of our approach to the Discussion (page 23).

4 Page 4: "CIs" should read "Chief Investigators (CIs)"

We have made this correction, thanks

5 Page 6:"Standardised observation schedule" - Can you give more detail on this?

Please see response 6 to reviewer 1.

6 Page 8: what does "TM" refer to?

Trial manager (now stated in text).

7 Page 8: Need for consistency when identifying the quotes: "trial" (line 53) whereas you refer to "RCT" in the rest of the quotes.

We have corrected to “RCT”

8 Page 10: "RCTl" should read "RCT"
We have made this correction, thanks

9 Page 12: "#38, Independent TSC member RCT 7" should read "#38, Independent TSC member, RCT 7"

We have made this correction, thanks