Author's response to reviews

Title: Clinical Trialist perspectives on the Ethics of Adaptive Clinical Trials: A Mixed-Methods Analysis

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Author's response to reviews: see over
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Dear Editors,

We thank the editors and the reviewers for their careful and thoughtful review of our manuscript. We have provided a point by point discussion of the feedback and provide description of what changes have been made to the manuscript responsive to these excellent suggestions.

1. RATS guidelines- In accordance with BioMed Central editorial policies (http://www.biomedcentral.com/about/editorialpolicies#StandardsofReporting), could you please ensure your manuscript reporting adheres to RATS guidelines (http://www.biomedcentral.com/authors/rats) for reporting qualitative studies. This is so your methodology can be fully evaluated and utilised.

We have reviewed the RATS guidelines. We have conducted mixed methods, so there we also conducted some quantitative survey research. The primary changes to the manuscript involve more description of the consent process.

Here are the specific issues from RATS that seem to merit more detail (we feel that the other items were well addressed by the existing manuscript.) Regarding the focus groups, no one declined. Regarding the surveys, we encouraged follow up but do not have information about the non-responders. We feel the design is well described, including the theories used in the textual analysis. Regarding the role of the researchers, the primary mixed methods team (LL and MDF) were researchers from outside the fields of neurological emergencies and clinical trial design. WM was also a member of the mixed methods team, but had a background in qualitative inquiry, clinical trial design, and neurological emergencies. Prior to ADAPT-IT, WM had no experience with adaptive clinical trials. Regarding anonymity, we ensured that individual participant responses would be difficult to attribute to any specific person and discussed that in the information process used for consent.

2. Written informed consent- Please state in the Methods section whether written informed consent for participation in the study was obtained from participants or, where participants are children, a parent or guardian.

All participants went through a consent procedure. Written informed consent is not required for most exempt survey research in the United States. We provided a handout / email in advance of data collection to participants that made it clear that the project was research, voluntary, and that they did not have to answer any questions they did not want to answer. We have adjusted the manuscript to succinctly indicate this.
3. Authors' Contributions- For manuscripts with more than one author, all BMC Series journals require an Authors’ Contributions section to be placed after the Competing Interests section.

We have added this.

4. Acknowledgement with details of any funding included.

We had this on the title page, we have moved to after the author contributions.