Author’s response to reviews

Title: Quality of intervention delivery in a cluster randomised controlled trial: a qualitative observational study with lessons for implementation fidelity

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Author’s response to reviews:

Dear Editors,

Please find attached a revised draft of our manuscript, titled: Quality of intervention delivery in a cluster randomised controlled trial: a qualitative observational study with lessons for fidelity. We are grateful for the opportunity to submit an amended version of our manuscript and would like to thank the reviewers for their helpful comments on our original submission, which has now been revised accordingly. We have listed our response to each comment below.

Reviewer 21.

Though the manuscript is well conceived, it is overwritten at times. The introduction can be condensed in order to more clearly indicate the added value of this study. We thank the review for this observation and have edited the introduction and removed a paragraph, making it more condensed.

2. Spelling mistakes and grammar need to be checked. We apologise for the errors in the writing, which have been corrected in the revised manuscript.

3. The distinction between the different sections could be improved by using formatted (sub)headings. We have now added numbered headings and subheadings for each section.

4. Please use a maximum of three to ten keywords. We have included ten keywords on page 3.

5. The authors refer to Bowers et al (2015) for in- and exclusion criteria. I think these can be informative here. This is a helpful suggestion and we have provided a description of inclusion/exclusion criteria, as follows (page 6 lines 21-24):

Inclusion criteria were acute psychiatric wards for adults of any gender. Wards were excluded if they had a specialist function, had planned major changes, or where two or more of the following criteria were met: no permanent ward manager in post, a locum consultant solely responsible for inpatient care, >30% nursing staff vacancy rate.

6. It would be interesting to know how the random allocation was implemented. We have now provided details of randomisation on page 6, lines 24-25; page 7 lines 1-6:

Three random selections were made: (i) hospitals, (ii) two wards at each hospital, (iii) allocation to experimental or control. Wards were randomly allocated to implement either the Safewards Intervention (‘Safewards’; n = 16 wards) or a comparator intervention designed to promote staff wellbeing so that they could support patients to the best of their ability (n = 15 wards). Simple randomisation was performed in each case by the designated...
The results of the fidelity analysis should be placed in the results section. We agree, and the results of the fidelity analysis can now be found in the results section (page 10, lines 22-23; page 11 lines 1-3). Means and standard deviations should be provided with every statistic (e.g. age). Mean fidelity scores are included on page 10, lines 22-23 and page 11, line 1. Unfortunately we do not have data for RA’s individual ages and so cannot provide a mean age for RAs. We would be happy to remove the age range if necessary.

The reason for using only the ‘most notable response’ could be explained more clearly. How did RAs decide which response was the most notable one (i.e. did they have guidelines in the handbook?) and why were not multiple notable responses collected instead of an overall response? We thank the reviewer for this observation. RAs were asked to record the most notable response rather than multiple notable responses because this approach would provide sufficient data to complete a robust analysis within the time constraints of the project (RAs returned 565 data sheets and recoding a number of notable observations would have increased the amount of data substantially, which would take a lot longer to analyse). In addition RAs had a limited amount of time available to complete and record their observations alongside other duties during ward visits, which included outcomes data collection, completion of the fidelity checklist, staff training and providing support with implementation. We have provided a more detailed explanation of the rationale for using the most notable response as follows (page 8, lines 20-25; page 10 lines 1-7): Because an aim of this study was to describe the variety of different ways in which the intervention was implemented, we documented the ‘most notable response’ rather than an overall response. This maximised our chances of capturing the full range of responses to implementation, because, for example, asking RAs to record an overall response was likely to return many descriptions of ‘protocol compliant’ implementation, and few, if any, of the more extreme responses, such as non-implementation or enhancement (Table X). It could also be difficult to gauge the ‘overall response’ of a ward where there may be a range of different responses from individual members of staff implementing an intervention. RAs were asked to record what the staff response meant to them and why, i.e. to explain why it was considered to be a notable response, and were given examples in training and written guidance (see below) as to what these might be, for example a positive response have felt like an important ‘breakthrough’, while a negative response may ‘concerning’ because it indicates a lack of trust.

The data analysis should be more elaborate. This is a helpful suggestion and we have now expanded the analysis section. Additional content is included in the following sections: page 11 (lines 8-24), 18 (lines 1-19). Similar to the background information, the discussion could be condensed in order to make a clearer statement on what can be learned from this study. We thank the reviewer for this observation and made edits to the discussion, making it shorter and more condensed.