Author’s response to reviews

Title: Community perspectives on randomisation and fairness in a cluster randomized controlled trial in Zambia

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Author’s response to reviews:

The Editor,
Journal for BMC Medical Ethics.

Dear Sir/Madam,


Reference is made to the above subject matter.

We are sincerely grateful and thankful for your time, the comprehensive, insightful comments, and expertise. Kindly be informed that we have made relevant corrections and modifications and we are now re-submitting the revised manuscript for further consideration.

Kindly find below this letter, an outline of how we have addressed the comments from the reviewers.

Yours sincerely,

Maureen Kombe and Ingvild Sandøy

Reviewer 1
Comment

This is a limited descriptive study of how participants in the RISE study perceived randomization. It is now clearer that although the participants perceived the process as transparent and as fair in the sense that the lottery itself was not rigged, they did not perceive the substantive structure of the trial as fair. That is, they did not understand why it was necessary to randomize in the first place (in order to understand the effects of the interventions) rather than allocating based on need. The rewritten draft brings out this contrast with greater clarity. This case study is a reasonable cautionary tale about the difficulties in explaining randomization--and may also be a cautionary tale about conducting randomization in these contexts as well.

Our response

Thank you so much for your comment

Reviewer 2

Comments

1. The authors have ably revised the manuscript to address most of my concerns in the initial review. They however, need to correct the typos and grammatical errors in the manuscript.

my main concern is with the conclusion. The authors state: for

The public randomisation ceremonies did not succeed in creating an understanding of the purpose of randomisation in a RCT was misunderstood by most of the respondents. However, the procedures of the public ceremonies were generally perceived as fair and transparent, and the fact that traditional leaders were part of the process reassured the respondents as they regarded them as impartial and accountable. For substantive fairness, people thought that the purpose of the "lottery" was to allocate aid and that the allocation should have been based on need rather than chance. The provision of clear and accurate information to participants about RCTs is important but this alone may not ensure consistent interpretation of core concepts such as randomisation or "lottery" and research. Thus formative research on how to better explain the concept of randomisation in lay language in the context where a RCT is planned, can be useful to ensure that

Our response

It looks the reviewer has not been able to see that we used track changes and that some of the words were deleted.

We have uploaded a version without track changes this time to make it easier to see what the text is meant to look like.
2. The sample size is very small and the views of the community as respondents was not captured. These are major limitations. Do the authors acknowledge other limitations and do they indicate how they were or could have been mitigated?

Our response

We have acknowledged that there could have been recall problems since the interviews were done 2 years after the randomization ceremonies.

A new sentence has been added in the discussion section, page…:”We thus recommend that future studies which explore how randomisation is understood in cluster randomised trials, also include the perceptions and experiences of trial participants themselves.”

3. The authors should indicate the key message as part of the conclusion of the study. They should also add the implications of their research findings for policy and practice, as well as for future research and community engagement. This is lacking from the discussions and conclusion.

Our response

We think that the key messages are mentioned in the conclusion with the first three sentences. Randomisation is a very research specific process and the findings of this study primarily have implications for future CRCTs, and thus we focus our recommendations on future research, but we have edited the final sentence slight to include the importance of community engagement:

“Thus formative research on how to better explain the concept of randomisation in lay language in the context where a RCT is planned, can be useful to ensure that the community engagement process helps research participants understand what to expect and do not withdraw because they think they have been unfairly treated. “