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:

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, a detailed outline of how we have addressed the comments from the reviewers. In responding to the comments, we have started with indicating the comment from reviewers, followed by our response. The page numbers have also been indicated in the response letter.

We would highly appreciate if our paper could be favorably considered for publication in the journal.

Yours faithfully,

Maureen Mupeta Kombe and Ingvild Sandøy
Additionally, there is a question about the ethics approval of the research study and the way it is obtained. It is not clear whether your study has been part of the Rise study and how the process of ethical approval for your study was obtained.

Our response

Yes, our study is part of the RISE project and the ethical approval obtained for RISE project applies also for our study. The reference number for the ethical approval from the University of Zambia Biomedical Research Ethics Committee is: 021-06-15. (Page 7).

Reviewer 1

Comment

The ethical conclusions drawn from the study are primarily about randomisation: that randomisation should be explained more clearly in lay language as a way to ensure that participants do not feel unfairly treated and do not withdraw prematurely from the study. I would, however, push the authors to consider several ethical questions further, if only to mention them as potential areas for exploration. One question is whether there were any ways in which characteristics of the participants might have affected their perceptions. The authors do note that they can assume education of 8 but not of other participants and they note gender. But they don't say anything further about whether these or other characteristics might have made a difference (or whether there was any way to have countered any bias in selection of participants). I'm especially interested in the gender question here because the RISE study was about the empowerment of girls, recognizing that their participants may perforce have been primarily male because of the makeup of the educational workforce participating in the study. To be fair, this is an exploratory study only, and the Ns are very small, but for further research it would be good to know if the authors have any data from the interviews that might be suggestive about whether there might be gender or educational or other differences in perceptions that researchers should consider addressing.

Our response

There were no gender differences in the reflections the respondents made about fairness related to the randomisation.

It is possible that the characteristics of educational level of the respondents could have an influence on the understanding of randomization process. However, we did not have educational background for all of them, and therefore, we can only mention this as a possibility. We have done that in the last paragraph of the Discussion.

Comment
Another question is whether what the study findings really reveal are not about understanding of randomization but about the design and ethics of this interventional trial itself. The authors state that the design of the trial was to evaluate whether material and economic support or material and economic support plus community dialogue was more effective in reducing early pregnancy. Yet it had a third arm, material support only. The research findings suggest that from the beginning people in the schools that got the most significant interventions believed that what they were getting was better than what others were getting. What impact these beliefs had on the research findings (did the schools with more resources do better because they believed they would, or because they got more resources?) is an open question. So, perhaps, is the question of the ethics of the research itself and whether the randomization was in any way in equipoise, especially with respect to the material support only group. While a full discussion of the ethics of trials with control arms in limited resource areas (and what people might be owed afterwards) is beyond the scope of this study, it would be helpful to have at least some reflection by the authors on this point and perhaps some references to the extensive literature discussing these issues with respect to RCTs. Given the study's aim as described by the authors here, why did the study include the material support arm only and not just the two other arms?

Our response

The question about equipoise is important, but in our opinion it is not relevant to the research question we examined in this paper which is whether the randomisation procedure was fair and transparent. We have thus only inserted some brief reflections about the respondents’ perceptions that one arm was better than the others in the Discussion section as a response to the reviewer’s concern.

Comment

Finally, although the authors introduce this study as about the ethics of CRCTs, their discussion does not comment on whether their findings suggest any differences in perceptions of fairness or other issues based on the fact that the randomization was across clusters rather than individuals. And, if there are differences, are they at all informative about the process of consent to participation in the trial or the obligations of researchers to the clusters after completion of the trial? Perhaps this is the most important of the further questions to encourage the authors to consider, given that their framing of their question is about CRCTs.

Our response

Allocation of interventions can exacerbate inequalities among groups of people and this can disturb communities, creating social disharmony. The respondents in this study compared their own community with other communities in relation to socioeconomic status and based their assessments of substantive fairness on perceived needs of different communities. However, when asked whether the allocation of the intervention was fair, several of the respondents also mentioned there was some jealousy and rumors in the community because only girls who enrolled in grade 7 in 2016 were eligible to participate in the trial, and parents of boys and girls in other grades found this to be unfair. This perceived unfairness did not have to do with the
randomisation as such, but clearly indicates that the trial contributed to social disharmony within the community. If the randomisation had been individual, it is likely that the fact that the participants within a community would not receive the same intervention, could have created even more social disharmony and reinforced perceptions of substantive unfairness. We have commented on this in the discussion now.

Reviewer 2

Comment

Abstract:

In lines 10-15, the authors in the abstract indicate that little is known about how participating individuals and communities understand and perceive central aspects of randomisation such as equality, fairness, transparency and accountability, in community-based trials. They found that randomisation was conducted for research purposes, but most of them did not. They had trouble distinguishing research and aid. Generally, respondents perceived the randomisation process as transparent and fair. They concluded that Randomisation was misunderstood by most respondents. Perceived procedural fairness was easier to realize than substantive fairness. The authors do not mention whether the respondents understood the central aspects (equality, fairness, transparency and accountability in community-based trials), or what respondents they perceived as the meaning of randomization in relation to the above central aspects.

Our response

Judging from the examples they gave, the respondents appeared to understand the central aspects of fairness, and transparency. They gave examples of elements that contributed to their perception of transparency. They described the process as open, without secrecy. We have now inserted some examples in the Results section. They added that there was nothing pre-determined.

The respondents did not use the concept of accountability directly themselves, but the way many of them talked about the role of the chiefs in the ceremony, indicated that they perceived the chiefs to be accountable superiors who did not have the interests of only one community in mind.

Example: R: Tell me, who went to the ceremony from your school?

P: It was myself, the head teacher of YY, the PTA chairperson and the chief representative of the ward. The chief representative was not representing our school only, he represented many schools in the area.

“We all saw what was happening and the people who were picking were chiefs. Can a chief take bribes against his own people?”
The respondents had different understandings of the concept of fairness. The majority focused on substantive fairness, which to them implied that everyone should receive the same benefits (here the term equality was brought in by a few respondents) or the benefits should be proportionate to people’s needs. A few of the respondents also used the term fairness in relation to the procedural aspects and argued that the process was fair because it was transparent and was not biased.

The respondents did not understand the rational of the randomisation. Although the term ‘lottery’ was used to depict and explain randomisation, this did not help. The respondents did not seem to understand that the randomisation aimed to achieve comparable study groups. Instead the respondents indicated that the study should not have conducted randomisation. They suggested that RISE project could have given out similar packages based on economic status of individuals and communities. We have now commented on this in the Discussion.

Background:

Comment

In lines 26-30, the authors state that Some of the reasons are that randomisation reduces bias, and facilitates blinding (masking) of the identity of treatments from researchers, participants and assessors, … and that use of clusters rather than individuals as randomization units is relevant when the interventions that are being studied address groups or communities. In lines 42-45, the authors further state that perceptions and experiences of participants regarding the following ethical issues related to the randomisation process were explored: fairness and equality, transparency and accountability. I think these are aspect that the authors should have explained further in relation to meaning of randomization. It is not clear whether and how the authors achieved this.

Our response

We have included more information about challenges related to the randomisation and why perceptions about fairness and transparency are relevant to explore in relation to randomisation. (Background section, Page 3 and 4). From an ethical perspective, a randomisation is fair when allocation to study arms is impartial and everyone has the same probability of being allocated to the different arms. Transparency and accountability imply that the randomisation procedure should be easy to understand and people should not perceive that there was potential manipulation (Page 3 and 4).

Comment

In lines 35-55, the authors ask questions about the randomization. They should have asked what happened, form the respondents’ view, rather that indicate to them that this was the randomization process. They should have asked what was done, and left it to the readers to judge whether the process was transparent, rather than ask respondents whether the process was transparent.
Likewise, the authors asked respondents whether the information given was (Line 45). To me this is misleading, as the authors should have asked what the respondents recalled as information given, and what this meant to them, in relation to the informed consent form or the study protocol. To me this is a major error.

Our response

Open ended questions like ‘what do you remember from randomisation ceremony of the RISE project conducted in July 2016?’, ‘Please tell me what happened at the randomisation ceremony for XX and YY districts’, ‘Can you tell me what information you received about randomisation before the ceremony?’ were asked before specific questions about transparency and clearness. Thus the initial responses to these open-ended questions made it possible to learn what their assessment was before asking closed questions. Most of the respondents mentioned transparency themselves before the interviewer mentioned the concept. In addition, the closed questions were followed by probing and paraphrasing to get a deeper understanding of the respondent’s point of view and perception of phenomena.

Comment

In the data analysis section, the authors state: The content of the data from interviews was explored at the end of each working day. The researchers reflected on the emerging materials, and adjusted the interview guides to enhance their relevance in subsequent days. I think this means that the interviews were not conducted in a similar manner. The authors should indicate the negative implications of changing the research instrument and data collection approach during the study, as well as the value addition, in case they found this necessary.

Our response

New information has been added (Page 6). Our study has applied a qualitative, explorative approach. Qualitative research is flexible and unique. It is fluid in nature and evolves throughout the research process. The data collection tool was an interview guide, which was flexible, and no fixed steps were followed. New questions, paraphrasing, and probing was applied in order to come to a deeper understanding of a phenomenon without diverting from the objectives of this study.

Comment

In the data analysis, the authors state: The meaning was analysed by identifying themes and patterns, that is, concepts, behaviours, interactions, incidents, terminology or phrases used, and they were organized into coherent categories that were summarized into codes. Themes and connections were used to explain the findings as well as attach meaning and significance to the analysis. They need to provide examples of how the codes were developed, and how the categories were generated. They also mention “behaviors”. This makes the data analysis process unclear.
Methods

The authors should give adequate details on the data collection and data analysis process

Our response

The Data collection

This section has been edited and new information added (page 5).

We have also added new information about the data analysis (Page 6). Data was categorized into themes and differences and similarities in themes were identified. Coding is not a precise science, it is primarily an interpretive act (Schurink et al., 2011). Below is an example on how codes were developed.

What I can say is that the process itself was very fair. It was fair because it was transparent. Where it wasn’t fair being that the gap between the packages on each school received. Here there was no fairness. Otherwise the conduct itself, was fair. But the gap in packages was just too big such that some of us felt that attending such a thing was a sheer waste of time. They were satisfied with the process that it was fair and transparent. But what they did not like were the groups.

-Process (Procedural fairness)
  1. FAIR
  2. TRANSPARENCY

-Gap between the packages (Substantive fairness)
  3. UNFAIRNESS

We have deleted the term “behavior” in the text to avoid confusion. What we meant was that when giving out answers, some respondents portrayed certain emotions such as frustration, anger which was in line with the verbal messages they gave out. Qualitative research is a form of inquiry in which researchers make an interpretation of what they see (observe including emotions), hear and understand (Schurink et al., 2011).

The findings

Comment

The authors do now show how, from the respondents’ vie, whether randomization achieved equality, fairness, transparency and accountability. This is a major fault of this study. For
instance, where respondents link fairness to spirituality, does that mean it is fair that those who prayed belong to one group and not the other, and does this relate to fairness? If so, in what sense?

The authors state that the process was transparent, and indicate this with just 2 short quotes of a few lines each. Yet what they claim was understood by respondents is explained in many words all of which may have different meaning to respondents. They state:

“Generally, all respondents mentioned that the randomisation process was transparent, fair and inclusive. Chiefs and/or their representatives conducted the process and were regarded to be responsible and accountable. There was no account about conflict of interest, voluntary participation was observed, the process was not biased and hence nobody mentioned suspicions of manipulation. Being able to witness the whole process was another aspect that people were happy with. They also mentioned that they did not know the people who were conducting the process. I have indicated the words in italics, which may require explanation, from the perspective of the respondents. I do not see the evidence that this is the meaning that respondents attached to the randomization process. The authors needed to indicate more information about what the respondents said, what meaning they attached to the responses, and how they assessed that respondents meant these and not the many other similar meanings that those terms could mean”.

Our response

New information has been added on Pages 9 and 10, as a response to these concerns. We have provided more quotes that illustrate how the respondents explained their perceptions.

Comment

On Equal chance and voluntarism, authors state:

“Although chiefs and/or their representatives were the ones who were given the opportunity to pick numbers from the box, they were not forced to do the task. There was no specific sequence of who should go first or last in line. There was no calling of names to go and pick the numbers”

The voluntarism should be about the community members who are recipients of the intervention, rather than the chiefs who represented them. In my opinion, they did not have a chance to belong to any group by chance. The process of picking the lottery does not indicate that there was an equal chance of belonging, either for the communities represented by the chief, or the individual members within each community. There was no equal choice in my opinion.

Our response

New information is added (Page 10). It was the respondents who used the term “voluntary participation” in relation to the chiefs and or their representatives participating in the randomisation process. According to respondents, there was no written list to follow in sequence
of who to pick the numbers from the boxes. The chiefs conducted the randomisation ceremony in the best interest of the people and for their communities. We agree with the reviewer that in relation to a trial, the most important aspect of voluntarism is that participation in the trial should be voluntary, and in order to avoid confusion we have deleted the word “voluntarism” from the subheading in the paper.

Comment

On fairness, the authors seem to suggest that transparency is equal to fairness. I believe this is not true, as not every transparent process is fair. Fairness relates to reasonableness, to justice, to equality of opportunity, to being realistic, to impartiality, to representativeness, to truthfulness. I am sure there were hypotheses that the cluster randomization wanted to study. Were the hypotheses reasonable, that all groups would not be different at the end of the different interventions? This does not seem to come out of the respondents’ view. Even for what is presented, it is not clear how it was derived.

Our response

New information has been added (Page 11). The authors are in agreement that transparency is not equal to fairness. However, the respondents used the concepts interchangeably. The presence of chiefs and/or their representatives suggested a fair process in their opinion. According to them, fairness depended on transparency.

Discussion

Comment

The authors seem to suggest that something done in a professional manner is fair, or that something done such that it leads to satisfaction implies that it was done fairly, or that something done according to plan means that it was done fairly. These are different meanings, despite some connection.

The authors also seem to imply that failure to understand the meaning of randomization is linked to unfairness, but this would also mean that understanding randomization would make it fair. This may not be the case, and the authors should explain why they think this is the case.

Our response

We are in agreement that the above words in question do not mean the same. However, respondents’ understanding and interpretation of these terms was suggestive that they perceived them as synonymous. For example, some of them said that fairness depended on transparency. We have now commented on this in the Discussion.
Comment

The authors state:

“Some respondents accused the RISE project to have further disadvantaged already vulnerable schools and explained that the RISE project should have considered the locality and environment of the schools before allocating packages. Some communities are located in remote areas and most of the parents are poor. They indicated that some schools that ended up in group three were located in non-remote areas and had parents employed in government and other parastatal organizations. They felt that the RISE project should have favored those who were socio-economically disadvantaged such as those in remote areas and peasant farmers”.

The authors should indicate what vulnerability they referred to as it related to the randomization process. They should have included suggestion from the respondents on what a fair randomization process should be (Procedural justice), or what results it would have (distributive justice). This does not seem to come out.

Our response

Vulnerability here referred to families or communities who cannot manage to take their children to schools because they are very poor economically and depended on yields from their fields for consumption only not for sale. To them the characteristic of economic status was the factor on which the RISE project should have based the allocation of packages.

According to the respondents, procedural justice was realized because they observed the randomisation process and it was transparent and fair. Distributive justice was not achieved as they thought it depended on the allocation of packages being based on need.

Comment

The authors suggest that understanding the purpose of randomization is key to perception of fairness and transparency. They should start by assessing whether randomization purpose was understood, and what the perceived purpose of randomization was, and why a better/different method of randomization was necessary.

Our response

New information has been added (Page 14). Respondents did not understand the purpose of the randomisation. They suggested that randomisation should not have been conducted and that allocating of packages was supposed to be based on needs. They also suggested that RISE project should have worked with community leaders to help identify those who are in dire need economically.
In the discussion, the authors further state:

Whilst communities were well informed during community engagement about the RISE project being a research study, this was not well understood. They however do not indicate any details for the community engagement, and whether the way it was conducted could be responsible for the different understanding or misunderstanding of the RISE project in general or randomization in particular. The readers, without details given, cannot make their independent judgement.

Our response

During the early community engagement, community members were well informed about the RISE project, including who was to run the project, the funder, what was involved in the project, why the project was to be conducted, who the target population was, the different packages and method of allocation. During interviews, respondents mentioned that they were well informed about such issues, however, the challenge was the understanding of the purpose of the randomisation and what research is in contrast to aid. It is likely that the project was perceived to be delivering aid because the interventions that would be tested were similar to support provided by different non-governmental organizations (NGOs).

Comment

The conclusion does not relate to the objectives and should be revised.

Our response

We have revised the conclusion section more clearly to relate to the objectives.