Reviewer’s report

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

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Reviewer: Daniel Kaye

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Comments

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

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.

Background:

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.

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.

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.

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

The findings

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”.

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.

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 hypothesis 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.

Ethics: It is not clear whether this was planned part of the RISE project, and ethical approval had been obtained earlier, or was a new study nested in an ongoing RISE project and reporting new data that needed ethical approval. The authors need to make this clarification

Discussion

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.
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.

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.

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 from 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.

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

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

No
Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

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Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

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