Reviewer’s report

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

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Reviewer: Leslie Francis

Reviewer's report:

This article addresses an important but limited ethical issue: the understanding of randomization among participants in clustered randomized controlled trials (CRTC). CRTC randomize between clusters rather than individuals, as the interventions under study address groups or communities rather than individuals. The article reports an exploratory study based on interviews with 14 subjects who participated in a study of research to enable the empowerment of girls (RISE) and, in addition, two tribal leaders. Central findings are that participants confused research and aid and that many did not understand randomization. The authors also report the apparent tension between procedural and substantive fairness in the beliefs of participants that the randomization process was fair and that it should tried to give different schools balanced benefits of the interventions based on their needs. The study presents important information about these perceptions but does not push its own ethical analysis as much as it might have done. In this review, I'll first present the article and findings and then make some suggestions about how the authors could be encouraged to press their own ethical analysis.

Interviews with participants were designed to explore their perceptions regarding fairness and equality, transparency, and accountability. Participants were selected from all three arms of the RISE study and from the different provinces in Zambia involved in the study. Only 2 of the 16 participants were female. Participants were between 30 and 50 years of age and were headmasters, teachers, or others associated with the schools included in the RISE study. A limitation of the study is that the interviews were conducted two years after the randomization and some participants in the study did not attend the randomization.

Structured interviews asked questions first about what participants remembered about the RISE randomization ceremony (in the RISE study in the effort to make the process clear, randomization was explained as a "lottery" and there was a ceremony in which the randomization took place). Then participants were asked whether the randomization was transparent and whether the information they were given was clear. They were asked how satisfied they were with the support package their school had been given. They were also asked about community attitudes towards what had been received.

One of the most interesting reported findings was that some participants did not understand the randomization as a "one-off" but thought that there would be another chance for their school to get a better package. Another is that participants appeared to believe from the beginning that some packages were "better" than others, although the RISE trial was designed to test the efficacy of different interventions. (The interventions were materials such as books and pencils;
materials and economic support; and materials, economic support, and community dialogue. The goal was to see whether material and economic support or material and economic support plus community dialogue reduced school dropout and early pregnancy most successfully. I can see why participants thought that "more" is better, but this article suggests not only that participants confused research with aid but also that they did not understand the research question. That is, they thought from the beginning that it would be best to be in the third group—so intensely that some prayed for the outcome before the randomization took place.). Recipients thus thought that packages should have been allocated based on the school's needs, rather than the randomization procedure.

The ethical conclusions drawn from the study are primarily about randomization: that randomization 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.

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?
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.

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If not, please specify what is required in your comments to the authors.

Yes

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