Reviewer's report

Title: Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting

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Reviewer: David Ellard

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Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting

Thank you for inviting me to review this article. I strongly believe that there needs to be more awareness of process evaluations in large clinical trials and as such I welcome the authors’ attempts to bring them to people’s attention. Indeed, funders should now be expecting research teams to not only report the effectiveness (or not of the trial) but also why it was effective (or not).

I do believe that process evaluations, like economic evaluations, should be designed, carried out and reported in all large trials.

This paper proposes a framework for the design and reporting of process evaluations. Whilst I acknowledge this is an important and indeed under reported area I do have some major concerns with the paper.

Background

Found this very limited in its scope. Process evaluation is not new it has roots in public health (and wider) and indeed the authors note it is often called other names (e.g. programme evaluation etc.) and as such we are not reinventing the wheel here. I am afraid the research councils have not yet caught up so there guidance on process evaluation is limited. Authors need to widen search and reference key papers (will explain more below).

Existing Literature

Ok clearly the purpose here was to look for cluster trials with a process evaluation and the authors find that there are very few; which is not surprising as even if they are done they are not often reported! However, there are good examples of process evaluations in public health these help to shape a framework for process evaluation which could be transferable/adapted to the rigors of a trial. I point the authors to a recent chapter (1) which, to some extent, provides ideas about how process evaluations can and should be included in trials. Yes, process evaluations are often qualitative but again the chapter mentioned above points out that the methods used should be appropriate to answer the question asked. Thus process evaluations of large trials, I suggest, would be of a mixed methods design. Yes you can quantify attendance and adherence but how do you know why people attended or didn’t? Similarly, you can count how many pills you give someone but how many do they actually
take? And why did/didn’t they take them?

Design of process evaluations are as important as the design of the trial itself and should be planned before the trial starts and if possible protocols published (see 2). It is in this way that they can be considered to have a similar scientific rigor.

Framework

The proposed framework is interesting but here I am really concerned about lack of reference to the work of Steckler & Linnan (3) who have proposed an excellent framework for process evaluations. Yes, I again acknowledge, that this volume is concerned with public health interventions but there are strong similarities to complex trials. Here again we find that methods used should be planned to answer the questions asked and generally a mixed methods approach is taken.

Reporting

Agree with much that is said here. Process evaluations, even limited ones, do not get published.

Thank you again for asking me to review this work and I wish you well with your future work.


**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

'I declare that I have no competing interests'