Reviewer's report

Title: Intervention description is not enough: evidence from an in-depth multiple case-study on the untold role and impact of context in RCTs of 7 Complex Interventions.

Version: 3 Date: 23 March 2012

Reviewer: Belinda Hall

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There is much discussion in the literature, particularly in the complex intervention space advocating for the importance of contextual factors in understanding and applying research findings. This paper takes this further by describing a novel approach to exploring the role of context using a multiple case study approach across a range of trials. The authors have explored various dimensions of context and presented empirical evidence to support their claims about the elements of context that are necessary to capture. The data presentation indicating the support for the various propositions across the included trials represents a logical approach to the task of data synthesis and is very useful to the reader.

Specific comments:

Major Compulsory Revisions
None

Minor Essential Revisions
1. The first part of the introduction appears to be missing some references. Paragraph 4 refers to previous work in the form of a number of single case reports, without providing any references to this work. This should be corrected.

Discretionary Revisions
2. The second last paragraph before the conclusion implies that researchers might be able to “find out” whether or not an intervention is working based on process data prior to the end of the trial. I would suggest that unless they are conducting appropriate analysis on effectiveness data throughout the duration of the trial that they would not be able to “find out” anything. Rather they may perceive that an intervention is not working well. It’s a very minor point, but I recommend changing the language from “find out” to “perceive”, especially given this is in the context of process data. Even if the researchers had access to effectiveness data, there would be stopping rules to consider before determining whether to act on it before the end of the trial.

3. Authors suggest in the abstract that “improved reporting formats that require and encourage the clarification of both general and project-specific threats to the
likely internal and external validity need to be developed". As the authors acknowledge, “the ways in which context challenged trial operation was often complex, idiosyncratic and subtle…", but I wonder if the authors could make some more specific suggestions about how current reporting formats could be improved. I appreciate this may be a topic for another study and publication, but thought readers (especially researchers designing and publishing studies of complex interventions) might appreciate some more specific pointers.

**Level of interest:** An article of importance in its field

**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.