Reviewer's report

Title: A Method to Reduce Imbalance for Site-Level Randomized Stepped Wedge Implementation Trial Designs

Version: 0 Date: 22 Oct 2018

Reviewer: Karla Hemming

Reviewer's report:

This is a much improved version of the earlier version. I would advise the authors to add some discussion of the unknown tertiary of what these restricted randomizations schemes should be trying to achieve. The authors argue that this type of balance is better than a type which balances the means across intervention and control conditions. However, no proof of this is provided. Type 1 error rates and power could be one way to investigate this - in further work.

Minor point: the authors say there is no control here. There is some sort of control and it might be that I am not using the same language as the authors to describe treatment and control conditions. I still suggest that the authors should either show the summary of the characteristics across treatment conditions, or sequences if they prefer.

The authors adopt the term 'sequential balance' and they say that they adopted this term because of my comments. However, my (implicit) suggestion was to use the term balance on sequence - which seems to be quite different to sequential balance. This leads me to another important point. I am not sure if the authors are balancing on sequence (which they call wave), and this point is still confusing to me. They say they balance on time, but the characteristics are not time varying.

In the balance equations T is represented as a linear effect and I wonder the implications of this?

The authors give the impression it might be permissible to search for the best balance allocation. However, others have shown that choosing the best balance inflates type 1 errors (see Moulton for a discussion of this). Others in this area therefore select one allocation from a subset of those with good balance.

The authors say there is no information on which to decide how to select those which have an acceptable level of balance and make an arbitrary decision to use the best 32 (I think). But, others have shown that 10% cut point works reasonably well in parallel trials - this might offer a starting point from which to explore the best choice for the cut point value.
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