Reviewer’s report

Title: Sample size calculation for a stepped wedge trial

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Reviewer: Moonseong Heo

Reviewer’s report:

This manuscript recommends application of simulation approach to determine sample sizes for various settings of stepped wedge trial (SWT) designs. To this end, this manuscript is well written with a comprehensive review of current literature on SWT designs. The proposed simulation approach is appealing and flexible given that closed-form sample size formulas, albeit preferable, could be intractable for certain complicated SWT designs that were discussed in the manuscript. The designs for the simulation studies are well thought-out with various combinations of SWT model parameters and different types of outcomes. However, the statistical models are somewhat simplistic even for the "cross-sectional" SWT. Specifically, although correlations (say ICC1), among outcomes within steps within clusters are considered, correlations (say ICC2) among outcomes between steps within clusters appear to be missing in all models under study. This kind of ICC2 might deserve consideration since the outcomes between steps are nested within the same clusters. For this reason, repeated-measure SWT designs may require another ICC over time points within individuals on top of ICC1 and ICC2 for that purpose. Comments on these issues are hoped.