Explaining the variation in the attained power of a stepped-wedge trial with unequal cluster sizes

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Abstract

**Background** In a cross-sectional stepped-wedge trial with unequal cluster sizes, attained power in the trial depends on the realized allocation of the clusters. This attained power may differ from the expected power calculated using standard formulae by averaging the attained power over all allocations the randomization algorithm can generate. We investigated the effect of design factors and allocation characteristics on attained power and developed models to predict attained power based on allocation characteristics.

**Method** Based on data simulated and analyzed using linear mixed-effects models, we evaluated the distribution of attained powers under different scenarios with varying intraclass correlation coefficient (ICC) of the responses, coefficient of variation (CV) of the cluster sizes, number of cluster-size groups, distributions of group sizes, and number of clusters. We explored the relationship between attained power and two allocation characteristics: the individual-level correlation between treatment status and time period, and the absolute treatment group imbalance. When computational time was excessive due to a scenario having a large number of possible allocations, we developed regression models to predict attained power using the treatment-vs-time period correlation and absolute treatment group imbalance as predictors.

**Results** The risk of attained power falling more than 5% below the expected or nominal power decreased as the ICC or number of clusters increased and as the CV decreased. Attained power was strongly affected by the treatment-vs-time period correlation. The absolute treatment group imbalance had much less impact on attained power. The attained power for any allocation was predicted accurately using a regression model that included linear and quadratic terms for the treatment-vs-time period correlation and a linear term for the absolute treatment group imbalance.

**Conclusion** In a stepped-wedge trial with unequal cluster sizes, the risk that randomization yields an allocation with inadequate attained power is a function of the ICC, the CV of the cluster sizes, and number of clusters. To reduce the computational burden of simulating attained power for allocations, the attained power can be predicted via regression modeling. Trial designers can reduce the risk of low attained power by restricting the randomization algorithm to avoid allocations with large
treatment-vs-time period correlations.

**Full Text**

Due to technical limitations, full-text HTML conversion of this manuscript could not be completed. However, the manuscript can be downloaded and accessed as a PDF.

**Figures**

![Diagram for a standard stepped-wedge cluster randomized controlled trial design. Cells in white correspond to periods of enrolment into the control intervention, cells in grey correspond to periods of enrolment into the new intervention.](image)

**Figure 1**

Diagram for a standard stepped-wedge cluster randomized controlled trial design. Cells in white correspond to periods of enrolment into the control intervention, cells in grey correspond to periods of enrolment into the new intervention.
Examples of power distributions: scenario 85 (48 clusters: 36 L (size: 56.99), 12 S (size: 9); CV:1.0; ICC:0.01), scenario 86 (48 clusters: 36 L (size: 67.85), 12 S (size: 10.72); CV:1.0; ICC:0.05). scenario 87 (48 clusters: 36 L (size: 75.99), 12 S (size: 12); CV:1.0; ICC:0.1).
The probability that the attained power falls more than five percent below the nominal (left set of panels) or the expected (right set of panels) power by ICC. The risks decreased as ICC increased in all scenarios, except for the ones with 12 clusters. Panel labels identify the total number of clusters (first line) and the distribution of clusters to the cluster size groups S:L or S:M:L (second line).
The probability that the attained power falls more than five percent below the nominal (left set of panels) or the expected (right set of panels) power by CV. The risks increased as CV increased in all scenarios except the ones with 12 clusters. The risks were near zero when the CV was smaller than 0.7, except for the scenarios with 12 clusters and two size groups. Panel labels identify the total number of clusters (first line) and the distribution of clusters to the cluster size groups S:L or S:M:L (second line).
The relationship between the transition time-points of the large clusters with TTC and TGI from one simulation run for a selected scenario (scenario 37: 24 clusters with 18S,6L). The trend is typical for other runs. The plotted number indicates the number of large clusters transitioning at end steps for that allocation. When all of the large clusters transition at the middle steps (number in green), TTC is high and TGI is low. When all of the large clusters transition at one end step (number in red), both TTC and TGI are low. When all of the large clusters transition equally split between the two ends (number in blue), TTC is low while TGI is high.
The relationship between treatment-vs-time period correlation and attained power among completed scenarios (A) and sampled scenarios (B). The attained power decreases considerably as the treatment-vs-time period correlation increases.
The relationship between treatment group imbalance and attained powers among completed scenarios (A) and sampled scenarios (B). A triangle pattern was observed in most scenarios. Large treatment group imbalances appeared to be associated with higher power.
Figure 8

Distribution of the coefficient for TGI before and after adjusting for TTC. Prior to adjustment, increasing TGI is associated with higher attained power in 90% of the scenarios. After adjustment, the direction of the association between TGI and attained power is inconsistent across the scenarios.
Figure 9

Contour plot of predicted attained power as a function of the treatment group imbalance and the treatment-time period correlation for scenario 79. The red dots correspond to the possible allocations in this scenario. The nearly vertical contour curves show that attained power is determined mainly by the treatment-time period correlation and the treatment group imbalance has only a small impact.
Figure 10

Side-by-side boxplots (upper panel) comparing the power distributions between evaluated and predicted attained powers for the sampled scenarios. For each scenario, the close overlap in the boxplots suggest that the evaluated results provide a reliable estimate for the entire set of allocations. The risks of the attained power falling more than five percent below the expected power on both evaluated and predicted distribution among sampled scenarios (lower panel) were very similar within each scenario.

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