

Summary of Submission for *Sample size and power calculations for designing stepped wedge cluster randomized trials with subclusters*

Introduction: This project provides an overview of the power and sample size calculations needed for designing stepped wedge cluster randomized trials when there is an additional level of clustering (i.e. subclusters) using a generalized linear mixed effects framework. R code is provided for generating power and sample size estimates for Gaussian/Normal outcomes and binary outcomes under a logit link when an equal number of subclusters per cluster and subcluster sizes are expected, and under the more relaxed assumption of varying numbers of subclusters per cluster and subcluster sizes using gamma density functions to characterize the distributions of the number of subclusters and subcluster sizes across clusters. The syntax may be used as an example or modified to fit a given study design.

Keyword Categories: cluster randomized trial, eigenvalues, extended block exchangeable correlation structure, generalized linear mixed models, power analysis

Genetics: Not Applicable (NA)

Statistical: Generalized linear mixed models; power analysis

Statistic Software: R

Component Files:

1. Presentation slides (PDF file) providing an overview of stepped wedge cluster randomized trials with subclusters, the methodology for generating the power and sample size, simulation study results to validate our developed methodology, and an example application. More detailed information can be found in the published paper (<https://doi.org/10.1111/biom.13596>).
2. Rcode (zip file) providing all R functions for generating power and sample size calculations as well as R code to reproduce all results from the published paper.

Optimal Use: The R functions can be used to generate power and sample size calculations for designing stepped wedge cluster randomized trials. The R code for the application examples shown in the published paper is included in the zip file and can be modified to generate the power and sample size for a specific stepped wedge cluster randomized trial design.

Prerequisites: Basic R knowledge is required to run the programs.

Potential Applications: Our R code can be easily modified to accommodate other types of longitudinal cluster randomized trial designs, such as longitudinal parallel and other crossover designs. Our R code can also be extended to other types of outcomes under the generalized linear mixed model framework and other density functions for characterizing the distribution of the number of subclusters and subcluster sizes across clusters.