

International Conference on Advances in Interdisciplinary Statistics and Combinatorics,
October 12–14, 2007, University of North Carolina at Greensboro, Greensboro, North
Carolina, USA

Coauthors: Hrishikesh Chakraborty, Waldemar A Carlo, Tyler D Hartwell, and
Linda L Wright

SAMPLE SIZE ADJUSTMENT TO MAINTAIN POWER IN CLUSTER RANDOMIZED TRIALS

JANET L. BARTZ

Adequately powered sample size calculation for cluster randomized trials primarily depends on the primary outcome variables distribution, effect size, average cluster size and intra-cluster correlation (ICC) estimates. Furthermore, the ICC estimate depends on the outcome variables distribution, cluster size, and number of clusters. Researchers often design cluster trials based on ICC estimates from previous trials or from a simulation. At the end of a trial, the distribution of the outcome variable often changes due to an effective intervention. Furthermore, since the ICC estimate depends on the outcome variables distribution, the ICC estimate will often change at the end of a trial. This change in the ICC estimate effects the sample size requirement and power for the trial. If the ICC estimate at the end of the trial is less than the ICC used for sample size calculation then the trial will be over powered. On the other hand, if the ICC estimate at the end of the trial is greater than the ICC used for sample size calculation then the inferences will be based on an under powered trial. Therefore, we need to adjust for this predicted ICC change during the design phase of a study when calculating the required sample size. To investigate these relationships we simulated data varying the outcome variable proportions, cluster sizes, and number of available clusters to determine the change in ICC estimates and their confidence intervals for different scenarios. The simulation results advocate adjusting the sample size during the design phase for potential changes to the ICC estimate at the end of the study in order to preserve the appropriate power and in some situations save trial cost. Two different trial examples were used to demonstrate different types of sample size adjustments during the design phase.

RTI INTERNATIONAL, RESEARCH TRIANGLE PARK, NORTH CAROLINA
E-mail address: jbartz@rti.org