SAMPLE SIZE CALCULATION ACCOUNTING FOR ATTRITION IN CLUSTER RANDOMIZED TRIALS

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In cluster randomized trials, naturally occurring clusters of individuals are randomized as intact groups to intervention and control conditions. Attrition arises when individual cluster members withdraw consent for data collection, or when decision makers at cluster-level withdraw entire clusters from the trial. We propose new sample size calculation formulas which account for either individual-level or cluster-level attrition. The formulas are derived using properties of Missing Completely At Random mechanisms, modeled by means of a standard approach for clustered binary data. The formulas account for potential loss of power due to the reduced study size, as well as the variability among cluster follow-up rates, which is shown to be a function of τ : the intracluster correlation coefficient for the missing data mechanism. Reporting of estimates for this parameter in published cluster randomized trials is recommended. A simulation study is used to show that the proposed sample size calculation formulas appropriately adjust for the missing data mechanism.