

## A Worked Example for an *A Priori* Stratified Analysis for a Simple Difference

The calculator will use the parameter estimates you have provided to calculate the required sample size of groups per condition x stratum cell for the intervention effect ( $\Delta$ ) and the level of power that you specified.

In addition, the calculator will use the other parameter estimates to calculate the detectable difference ( $\Delta$ ) that is available with the level of power that you specified as a function of the number of groups ( $g$ ) in each condition x stratum cell and the number of members ( $m$ ) in each group, using the formula below.

$$\Delta = \sqrt{2 \times 2 \left( \frac{\left( \sigma_y^2 (1 - \text{ICC}) (1 - R_{y \cdot x_m}^2) (1 - r_{y s_m}) + m \sigma_y^2 (\text{ICC}) (1 - R_{y \cdot x_g}^2) (1 - r_{y s_g}) \right)}{mg} \right) \left( t_{\alpha/2} + t_{\beta} \right)^2}$$

Here  $\sigma_y^2$  is the variance of the outcome variable ignoring any expected ICC, ICC is the intraclass correlation among the members in the same group,  $R_{y \cdot x_m}^2$  is the proportion of variance explained by the member-level covariates,  $r_{y s_m}$  is the correlation between the outcome variable and the stratification variable at the level of the member,  $m$  is the number of members in each group,  $R_{y \cdot x_g}^2$  is the proportion of variance explained by the group-level covariates,  $r_{y s_g}$  is the correlation between the outcome variable and the stratification variable at the level of the group,  $g$  is the number of groups or clusters in the each condition x stratum cell,  $t_{\alpha/2}$  is the t-value selected based on the two-tailed alpha level and available degrees of freedom, and  $t_{\beta}$  is the t-value selected based on the desired power and available degrees of freedom.

As an example, consider the following set of parameter estimates:

Let  $m = 100$  and  $g = 25$  with  $x_m = 4$  df used for member-level covariates and  $x_g = 1$  df used for group-level covariates. Then

$$df = cs(g - 1) - df_g = 2 \times 2(25 - 1) - 1 = 95$$

For a two-tailed type 1 error rate of 5% and power of 80%,

$$t_{\alpha/2} = 1.9853 \text{ and } t_{\beta} = 0.8454$$

Let  $\sigma_y^2 = 1.0$  and  $\text{ICC} = 0.05$ .

Let  $R_{y \cdot x_m}^2 = 0.70$  and  $R_{y \cdot x_g}^2 = 0.10$ .

Let  $r_{y s_m} = 0.20$  and  $r_{y s_g} = 0.00$ .

Then

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$$\Delta = \sqrt{2 \times 2 \left( \frac{(1(1-0.05)(1-0.7)(1-0.2) + 100(1)(0.05)(1-0.1)(1-0))}{100 \times 25} \right)} (1.9853 + 0.8454)^2$$
$$= 0.2462$$

The detectable difference given these parameter estimates is 0.2462 standard deviation units.