

## A Worked Example for an *A Priori* Stratified Analysis of a Net Difference in a Cross-Sectional Design

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. Note: this formula is for a cross-sectional design, so that  $(1 - r_{yy_m})$  has been removed from the left-hand side of the numerator.

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

Here 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,  $r_{ys_m}$  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,  $r_{ys_g}$  is the correlation between the outcome variable and the stratification variable at  $\sigma_y^2$  the level of the group,  $r_{yy_g}$  is the overtime correlation for the outcome 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  $g = 48$  with  $x_m = 4$  df used for member-level covariates and  $x_g = 1$  df used for group-level covariates. Then

$$df = (t - 1)cs(g - 1) - df_g = (2 - 1)2 \times 2(48 - 1) - 1 = 187$$

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

$$t_{\alpha/2} = 1.9727 \text{ and } t_{\beta} = 0.8435$$

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

Let  $R_{y \cdot x_m}^2 = 0.20$  and  $R_{y \cdot x_g}^2 = 0.00$ .

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Let  $r_{y_s_m} = 0.10$  and  $r_{y_s_g} = 0.00$ .

Let  $r_{y_y_g} = 0.20$ .

Then

$$\Delta = \sqrt{2 \times 2 \times 2 \left( \frac{(1(1-0.05)(1-0.2)(1-0.1) + 100(1)(0.05)(1-0)(1-0)(1-0.2))}{100 \times 48} \right) (1.9727 + 0.8435)^2}$$
$$= 0.2488$$

The detectable difference given these parameter estimates is 0.2488 standard deviation units.