

The assumptions surrounding the values of $\mu_1 - \mu_2$ and σ , however, are certainly beyond control, and quite often, very uncertain. In these cases, it is very practical to consider a range of plausible values when determining the sample size to be utilized in a given study. It should be noted that the sample size formula can be rewritten as:

$$n = 2 \left(\frac{1}{\theta} \right)^2 (z_{1-(\alpha/2)} + z_{1-\beta})^2$$

where $\theta = (\mu_1 - \mu_2)/\sigma$. The value of θ is sometimes referred to as the population effect size, which is the standardized mean difference between two populations. Given that the formula is multiplicative in $1/\theta$ and $(z_{1-(\alpha/2)} + z_{1-\beta})$, it is clear that increases in the value of $(z_{1-(\alpha/2)} + z_{1-\beta})$ while holding $1/\theta$ constant will lead to increases in sample size. Similarly, decreases in the value of $(z_{1-(\alpha/2)} + z_{1-\beta})$ while holding $1/\theta$ constant will lead to decreases in sample size. When considering changes to the population effect size, θ , it should be noted that larger values of θ will yield smaller values of $1/\theta$. Hence, increasing the effect size while holding $(z_{1-(\alpha/2)} + z_{1-\beta})$ constant, will yield smaller sample sizes (as $1/\theta$ will be smaller), and decreasing the effect size while holding $(z_{1-(\alpha/2)} + z_{1-\beta})$ constant, will yield larger sample sizes (as $1/\theta$ will be larger).

IX. CHANGING ASSUMPTIONS ABOUT ALPHA (α) OR BETA (β)

Consider the following, suppose a company is considering study design *A* with an effect size of θ , $1-\beta_a$ power, and type I error of α_a and study design *B* has an effect size of θ , $1-\beta_b$ power, and type I error of α_b . The relative size difference between the two designs

can then be written as the ratio of the two sample sizes:

$$\frac{n_A}{n_B} = \frac{2(1/\theta)^2 (z_{1-(\alpha_a/2)} + z_{1-\alpha_a})^2}{2(1/\theta)^2 (z_{1-(\alpha_b/2)} + z_{1-\alpha_b})^2}$$

After reducing the fraction by removing common terms, the equation becomes simply a ratio of quantities that can be obtained from [Table 10.2](#), as:

$$\frac{n_A}{n_B} = \frac{(z_{1-(\alpha_a/2)} + z_{1-\alpha_a})^2}{(z_{1-(\alpha_b/2)} + z_{1-\alpha_b})^2}$$

For example, if study design *A* has 90% power and a type I error rate of 5% and study design *B* has 80% power and a type I error rate of 5%, the equation becomes:

$$\frac{n_A}{n_B} = \frac{(z_{1-(0.05/2)} + z_{1-0.1})^2}{(z_{1-(0.05/2)} + z_{1-0.2})^2}$$

$$\frac{n_A}{n_B} = \frac{10.5}{7.8} = 1.35$$

Here, we see that the size difference for these two designs is 35%. Recall in [Example 1](#) of this section, the calculated sample sizes per group were 131.5 and 97.5 for 90% and 80% power, respectively. Taking the ratio of these two values verifies the calculation above:

$$\frac{n_A}{n_B} = \frac{131.5}{97.5} = 1.35$$

Given this relationship, it is easy to transform the values in [Table 10.2](#) to relative efficiencies of two designs with the same effect size, but varying values of α and β . This can be done by choosing a reference design, say $\alpha = 0.05$ and $\beta = 0.2$, and then dividing each value of the quantity $(z_{1-(\alpha/2)} + z_{1-\beta})^2$ contained in the table by the corresponding value of $(z_{1-(\alpha/2)} + z_{1-\beta})^2$ for the reference design, here, 7.8. These values are presented in [Table 10.4](#).