

1. Mean difference

(two independent / unpaired groups)

$$n_{per\ group} = 2 * \left(\frac{(Z_{1-\alpha} + Z_{1-\beta}) * SD_{pooled}}{d} \right)^2$$

or: $n = \frac{2 * (Z_{1-\alpha} + Z_{1-\beta})^2 * SD^2}{d^2}$

$Z_{1-\alpha}$ = standard normal derivative for the type 1 error (value from std normal distribution (mean=0, SD=1) (MS Excel function NORM.INV or NORMSINV)

$Z_{1-\beta}$ = standard normal derivative for the type 2 error (value from standard normal distribution (mean=0, SD=1); (MS Excel function NORM.INV or NORMSINV)

SD_{pooled} = standard deviation pooled from both groups (SD is based on the spread within each group)

d = difference between group means

2. Mean difference

(1 group, pre-post repeated measures / paired)

$$n = \left(\frac{(Z_{1-\alpha} + Z_{1-\beta}) * SD_{diff}}{d} \right)^2$$

$Z_{1-\alpha}$ = standard normal derivative for the type 1 error (value from std normal distribution (mean=0, SD=1) (MS Excel function NORM.INV or NORMSINV)

$Z_{1-\beta}$ = standard normal derivative for the type 2 error (value from standard normal distribution (mean=0, SD=1); (MS Excel function NORM.INV or NORMSINV)

SD_{diff} = standard deviation of the difference (SD is based on how much people differ from themselves, not from others)

d = difference between means

3. Proportion difference **(two independent / unpaired groups)**

$$n = \frac{(Z_{1-\alpha} + Z_{1-\beta})^2 * p_c(1 - p_c) + p_t(1 - p_t)}{(p_c - p_t)^2}$$

$Z_{1-\alpha}$ = standard normal derivative for the type 1 error (value from std normal distribution (mean=0, SD=1) (MS Excel function NORM.INV or NORMSINV)

$Z_{1-\beta}$ = standard normal derivative for the type 2 error (value from standard normal distribution (mean=0, SD=1); (MS Excel function NORM.INV or NORMSINV)

p_c = proportion of subjects having the event in the control (placebo) group

p_t = proportion of subjects having the event in the treatment group (percent in control group reduced by the treatment)

4. Proportion difference (simplified approximation) **(1 group, pre-post repeated measures / paired)**

$$n = \frac{(Z_{1-\alpha} + Z_{1-\beta})^2 * (P_{01} + P_{10})}{(P_{01} - P_{10})^2}$$

$Z_{1-\alpha}$ = standard normal derivative for the type 1 error (value from std normal distribution (mean=0, SD=1) (MS Excel function NORM.INV or NORMSINV)

$Z_{1-\beta}$ = standard normal derivative for the type 2 error (value from standard normal distribution (mean=0, SD=1); (MS Excel function NORM.INV or NORMSINV)

P_{01} = proportion who change from 0 → 1 (improve)

P_{10} = proportion who change from 1 → 0 (worsen)

5. Questionnaire

$$n = \frac{\frac{Z_{(1-\alpha)/2}^2 p(1-p)}{e^2}}{1 + \left(\frac{Z_{(1-\alpha)/2}^2 p(1-p)}{e^2 N} \right)}$$

Z_{α} = confidence level from standard normal derivative for the type 1 error (value from std normal distribution (mean=0, SD=1) (MS Excel function NORM.INV or NORMSINV)

p = response distribution

e = margin of error

N = population size

6. Supplementary calculations

a. Factor to increase sample size for non-compliance

$$\frac{1}{(1 - a - b)^2}$$

a = proportion of drop-outs

b = proportion of drop-ins

b. Factor to increase sample size for loss to follow-up

$$\frac{1}{1 - c}$$

c = proportion of lost to follow-up