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Documentation of Power for Randomized Clinical Trials

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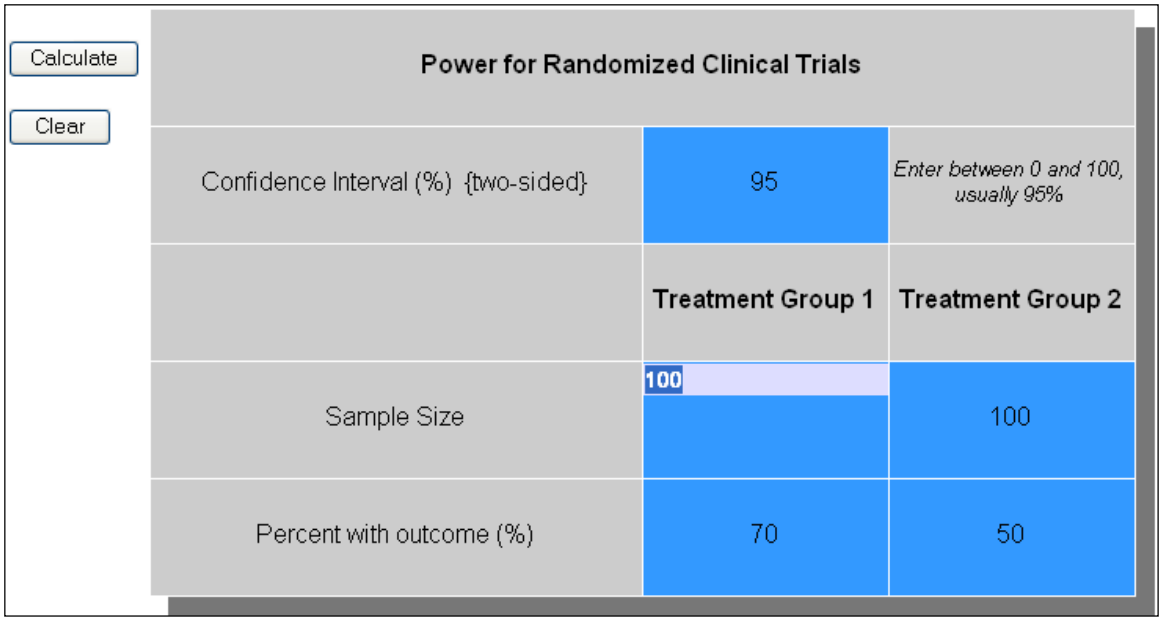
This module estimates power for randomized clinical trials. The data input screen is as follows:



The input values requested are:

- Two sided confidence intervals (%) that can be chosen are 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 98, 99, 99.5, 99.8, 99.9, 99.95, 99.98 & 99.99.
- The available sample size for Treatment Group 1 and that for Treatment Group 2 are entered.
- The percent (proportion) of outcome in Treatment Group 1 and Treatment Group 2 are entered ranging from 0 to 100%.

The result of the calculation is shown next:

Power for Randomized Clinical Trials

	Input Data
Two sided-confidence interval (%)	95
Sample size of Treatment Group 1	100
Percent with outcome in Treatment Group 1 (%)	70
Sample size of Treatment Group 2	100
Percent with outcome in Treatment Group 2 (%)	50
Risk ratio detected	1.4

Power based on:	
Normal approximation	82.81%
Normal approximation with continuity correction	78.68%

Results from OpenEpi open source calculator--PowerRCT

file:///C:/OpenEpi/July,%202005/Power/PowerRCT.htm
Source file last modified on 07/11/2005 14:23:58

Print from the browser, or select all or part of the text and then copy and paste to other programs.
Many browsers have an optional setting to print background colors.

The interpretation of power in this clinical trial is as follows: If, in truth, Treatment Group 1 differs from Treatment Group 2 in their outcome given the above values, this study would have 83% chance of detecting a difference without continuity correction.

The formulae for the estimation of power are as follows:

- *Power with normal approximation:*

$$Power = \Phi\left(\frac{\sqrt{(n_1 * \Delta^2)} - z_{1-\alpha/2}\sqrt{(1+1/\kappa) * p * q}}{\sqrt{(p_1 * q_1) + (p_2 * q_2 / \kappa)}} \right)$$

- *Power with continuity correction:*

$$Power = \Phi\left(\frac{\sqrt{(n' * \Delta^2)} - z_{1-\alpha/2}\sqrt{(1+1/\kappa) * p * q}}{\sqrt{(p_1 * q_1) + (p_2 * q_2 / \kappa)}} \right)$$

Where **n'** = n_1 - [(κ +1) / (κ . Δ)];

- *Risk ratio calculation*

RR = (p_1/p_2);

The notations for the formulae are:

Δ = difference of percent of outcome between Treatment Group-1 and Treatment Group-2;

κ = ratio of sample size: Treatment Group-2 / Treatment Group-1;

p_1= percent of outcome in Treatment Group-1;

p_2= percent of outcome in Treatment Group-2;

p = (p_1*n_1+p_2*n_2) / (n_1+n_2);

q= 1-p;

n_1= sample size of Treatment Group-1;

References:

- James Schlesselman. Case-control studies: Design, Conduct, Analysis (1982). (Formula 6.9 is used for estimation of power)
- Sahai H and KHurshid A. Formulae and tables for the determination of sample sizes and power in clinical trials for testing differences in proportions for the two-sample design: A review. *Statistics in Medicine*, 1996 vol. 15, 1-21. ((In addition to formula 6.9 mentioned above, formula 23 is used to calculate power with continuity correction)

Acknowledgement:
Data in input screen are obtained from example 10.28 in "Bernard Rosner. Fundamentals of Biostatistics (5^{th} edition)".