Sample Size Calculator

Determines the minimum number of subjects for adequate study power

Study Group Design

vs.
Two independent study groups

vs.
One study group vs. population

Two study groups will each receive different treatments.

Primary Endpoint

Dichotomous (yes/no)

Continuous (means)

The primary endpoint is **binomial** - only two possible outcomes.
Eg, mortality (dead/not dead), pregnant (pregnant/not)

Statistical Parameters

Anticipated Incidence

Group 1 (?) 90.11 %

Group 2 (?) 77.25 %

Incidence

Enrollment ratio (?) 1

Type I/II Error Rate

Alpha (?) 0.05

Power (?) 80%

Reset **Calculate**

RESULTS

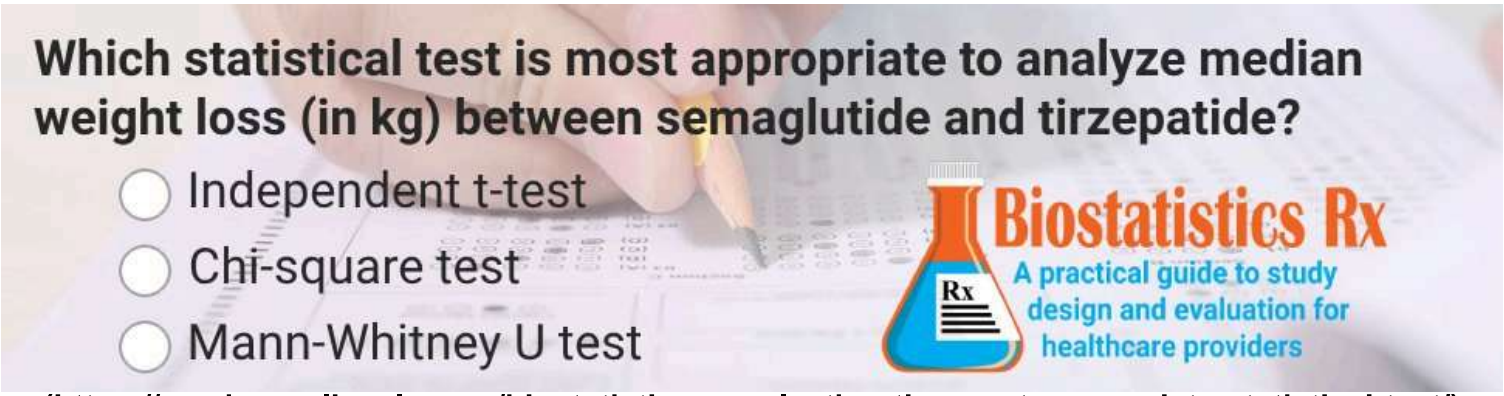
Dichotomous Endpoint, Two Independent Sample Study

Sample Size	
Group 1	128
Group 2	128
Total	**256**

Study Parameters

Incidence, group 1	90.11%
Incidence, group 2	77.25%
Alpha	0.05
Beta	0.2
Power	0.8

View Power Calculations



(https://academy.clincalc.com/biostatistics-rx-selecting-the-most-appropriate-statistical-test/)

About This Calculator

This calculator uses a number of different equations to determine the minimum number of subjects that need to be enrolled in a study in order to have sufficient statistical power to detect a treatment effect.[1]

Before a study is conducted, investigators need to determine how many subjects should be included. By enrolling too few subjects, a study may not have enough statistical power to detect a difference (type II error). Enrolling too many patients can be unnecessarily costly or time-consuming.

Generally speaking, statistical power is determined by the following variables:

- **Baseline Incidence:** If an outcome occurs infrequently, many more patients are needed in order to detect a difference.
- **Population Variance:** The higher the variance (standard deviation), the more patients are needed to demonstrate a difference.
- **Treatment Effect Size:** If the difference between two treatments is small, more patients will be required to detect a difference.

- **Alpha:** The probability of a type-I error -- finding a difference when a difference does not exist. Most medical literature uses an alpha cut-off of 5% (0.05) -- indicating a 5% chance that a significant difference is actually due to chance and is not a true difference.
- **Beta:** The probability of a type-II error -- not detecting a difference when one actually exists. Beta is directly related to study power (Power = 1 - β). Most medical literature uses a beta cut-off of 20% (0.2) -- indicating a 20% chance that a significant difference is missed.

Post-Hoc Power Analysis

To calculate the post-hoc statistical power of an existing trial, please visit the **post-hoc power analysis calculator (Power.aspx)**.

References and Additional Reading

1. Rosner B. *Fundamentals of Biostatistics*. 7th ed. Boston, MA: Brooks/Cole; 2011.

- Introducing RxFlip: The Ultimate App for Learning the Top 250 Drugs (//clincalc.com/blog/2025/02/introducing-rxflip-the-ultimate-app-for-learning-the-top-250-drugs/)
- ClinCalc DrugStats: Most Commonly Prescribed Medications in 2021 (//clincalc.com/blog/2024/01/clincalc-drugstats-most-commonly-prescribed-medications-in-2021/)
- ASCVD Risk Calculator (/Cardiology/ASCVD/PooledCohort.aspx)

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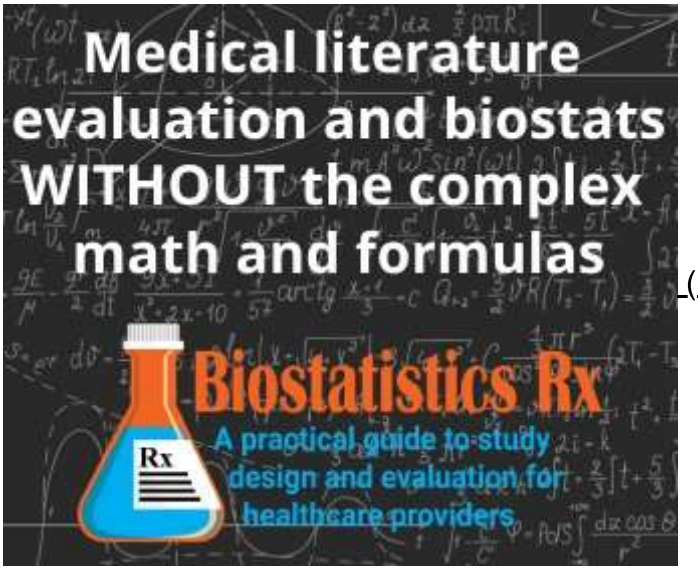

(https://academy.clincalc.com/enroll-biostatistics-rx/)