Chapter 472

Confidence Intervals for the Difference Between Two Means with Tolerance Probability

Introduction

This procedure calculates the sample size necessary to achieve a specified distance from the difference in sample means to the confidence limit(s) with a given tolerance probability at a stated confidence level for a confidence interval about the difference in means when the underlying data distribution is normal.

Sample sizes are calculated only for the case where the standard deviations are assumed to be equal, wherein the pooled standard deviation formula is used.

Technical Details

Let the means of the two populations be represented by μ_1 and μ_2, and let the standard deviations of the two populations be represented as σ_1 and σ_2.

When $\sigma_1 = \sigma_2 = \sigma$ are unknown, the appropriate two-sided confidence interval for $\mu_1 - \mu_2$ is

$$\bar{X}_1 - \bar{X}_2 \pm t_{1-\alpha/2,n_1+n_2-2} s_p \sqrt{\frac{1}{n_1} + \frac{1}{n_2}}$$

where

$$s_p = \sqrt{\frac{(n_1-1)s_1^2 + (n_2-1)s_2^2}{n_1+n_2-2}}$$

Upper and lower one-sided confidence intervals can be obtained by replacing α / 2 with α.

The required sample size for a given precision, *D*, can be found by solving the following equation iteratively

$$D = t_{1-\alpha/2,n_1+n_2-2} s_p \sqrt{\frac{1}{n_1} + \frac{1}{n_2}}$$

This equation can be used to solve for *D* or n_1 or n_2 based on the values of the remaining parameters.

There is an additional subtlety that arises when the standard deviation is to be chosen for estimating sample size. The sample sizes determined from the formula above produce confidence intervals with the specified widths only when the future samples have a pooled standard deviation that is no greater than the value specified.

As an example, suppose that 15 individuals are sampled from each population in a pilot study, and a pooled standard deviation estimate of 5.4 is obtained from the sample. The purpose of a later study is to estimate the difference in means within 10 units. Suppose further that the sample size needed is calculated to be 62 per group using the formula above with 5.4 as the estimate for the pooled standard deviation. The samples of size 62 are then obtained from each population, but the pooled standard deviation turns out to be 6.3 rather than 5.4. The confidence interval is computed and the distance from the difference in means to the confidence limits is greater than 10 units.

This example illustrates the need for an adjustment to adjust the sample size such that the distance from the difference in means to the confidence limits will be below the specified value with known probability.

Such an adjustment for situations where a previous sample is used to estimate the standard deviation is derived by Harris, Horvitz, and Mood (1948) and discussed in Zar (1984). The adjustment is

$$D = t_{1-\alpha/2,n_1+n_2-2} s_p \sqrt{\frac{1}{n_1} + \frac{1}{n_2}} \sqrt{F_{1-\gamma;n_1+n_2-2,m_1+m_2-2}}$$

where $1 - \gamma$ is the probability that the distance from the difference in means to the confidence limit(s) will be below the specified value, and m_1 and m_2 are the sample sizes in the previous samples that were used to estimate the pooled standard deviation.

The corresponding adjustment when no previous sample is available is discussed in Kupper and Hafner (1989). The adjustment in this case is

$$D = t_{1-\alpha/2,n_1+n_2-2} s_p \sqrt{\frac{1}{n_1} + \frac{1}{n_2}} \sqrt{\frac{\chi^2_{1-\gamma,n_1+n_2-2}}{n_1 + n_2 - 2}}$$

where, again, $1 - \gamma$ is the probability that the distance from the difference in means to the confidence limit(s) will be below the specified value.

Each of these adjustments accounts for the variability in a future estimate of the pooled standard deviation. In the first adjustment formula (Harris, Horvitz, and Mood, 1948), the distribution of the pooled standard deviation is based on the estimate from previous samples. In the second adjustment formula, the distribution of the pooled standard deviation is based on a specified value that is assumed to be the population pooled standard deviation.

Confidence Level

The confidence level, $1 - \alpha$, has the following interpretation. If thousands of samples of n_1 and n_2 items are drawn from populations using simple random sampling and a confidence interval is calculated for each sample, the proportion of those intervals that will include the true population mean difference is $1 - \alpha$.

Notice that is a long-term statement about many, many samples.

Example 1 – Calculating Sample Size

Suppose a study is planned in which the researcher wishes to construct a two-sided 95% confidence interval for the difference between two population means. It is very important that the mean weight is estimated within 10 units. The pooled standard deviation estimate, based on the range of data values, is 25.6. Instead of examining only the interval half-width of 10, a series of half-widths from 5 to 15 will also be considered.

The goal is to determine the sample size necessary to obtain a two-sided confidence interval such that the difference in means is estimated within 10 units. Tolerance probabilities of 0.70 to 0.95 will be examined.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 1** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab

Solve For	**Sample Size**
Interval Type	**Two-Sided**
Confidence Level (1 - Alpha)	**0.95**
Tolerance Probability	**0.70 to 0.95 by 0.05**
Group Allocation	**Equal (N1 = N2)**
Distance from Mean Difference to Limit(s)	**10**
Standard Deviation Source	**S is a Population Standard Deviation**
S (Standard Deviation)	**25.6**

Output

Click the Calculate button to perform the calculations and generate the following output.

Numeric Reports

Numeric Results

Solve For: Sample Size
Interval Type: Two-Sided

Confidence Level	Sample Size N1	N2	N	Distance from Mean Difference to Limits: Target	Actual	Pooled Standard Deviation	Tolerance Probability
0.95	55	55	110	10	9.994	25.6	0.70
0.95	56	56	112	10	9.998	25.6	0.75
0.95	58	58	116	10	9.919	25.6	0.80
0.95	59	59	118	10	9.951	25.6	0.85
0.95	61	61	122	10	9.921	25.6	0.90
0.95	63	63	126	10	9.962	25.6	0.95

Confidence Level	The proportion of confidence intervals (constructed with this same confidence level, sample size, etc.) that would contain the true difference in population means.
N1 and N2	The number of items sampled from each population.
N	The total sample size. N = N1 + N2.
Distance from Mean Difference to Limits	The distance from the confidence limit(s) to the difference in sample means.
Target Distance	The value of the distance that is entered into the procedure.
Actual Distance	The value of the distance that is obtained from the procedure.
Pooled Standard Deviation	The standard deviation upon which the distance from mean difference to limit calculations are based.
Tolerance Probability	The probability that a future interval with sample size N and corresponding confidence level will have a distance from the mean to the limit(s) that is less than or equal to the specified distance.

Summary Statements

A parallel two-group design will be used to obtain a two-sided 95% confidence interval for the difference between two means. The standard deviations of the two groups are assumed to be equal and the pooled-variance t-distribution formula will be used to calculate the confidence interval. The population standard deviation for both groups is assumed to be 25.6. To produce a confidence interval with 0.7 probability that the distance from the sample mean difference to either limit will be no more than 10, the number of subjects needed will be 55 in Group 1 and 55 in Group 2.

Dropout-Inflated Sample Size

	Sample Size			Dropout-Inflated Enrollment Sample Size			Expected Number of Dropouts		
Dropout Rate	**N1**	**N2**	**N**	**N1'**	**N2'**	**N'**	**D1**	**D2**	**D**
20%	55	55	110	69	69	138	14	14	28
20%	56	56	112	70	70	140	14	14	28
20%	58	58	116	73	73	146	15	15	30
20%	59	59	118	74	74	148	15	15	30
20%	61	61	122	77	77	154	16	16	32
20%	63	63	126	79	79	158	16	16	32

Dropout Rate The percentage of subjects (or items) that are expected to be lost at random during the course of the study and for whom no response data will be collected (i.e., will be treated as "missing"). Abbreviated as DR.
N1, N2, and N The evaluable sample sizes at which the confidence interval is computed. If N1 and N2 subjects are evaluated out of the N1' and N2' subjects that are enrolled in the study, the design will achieve the stated confidence interval.
N1', N2', and N' The number of subjects that should be enrolled in the study in order to obtain N1, N2, and N evaluable subjects, based on the assumed dropout rate. After solving for N1 and N2, N1' and N2' are calculated by inflating N1 and N2 using the formulas N1' = N1 / (1 - DR) and N2' = N2 / (1 - DR), with N1' and N2' always rounded up. (See Julious, S.A. (2010) pages 52-53, or Chow, S.C., Shao, J., Wang, H., and Lokhnygina, Y. (2018) pages 32-33.)
D1, D2, and D The expected number of dropouts. D1 = N1' - N1, D2 = N2' - N2, and D = D1 + D2.

Dropout Summary Statements

Anticipating a 20% dropout rate, 69 subjects should be enrolled in Group 1, and 69 in Group 2, to obtain final group sample sizes of 55 and 55, respectively.

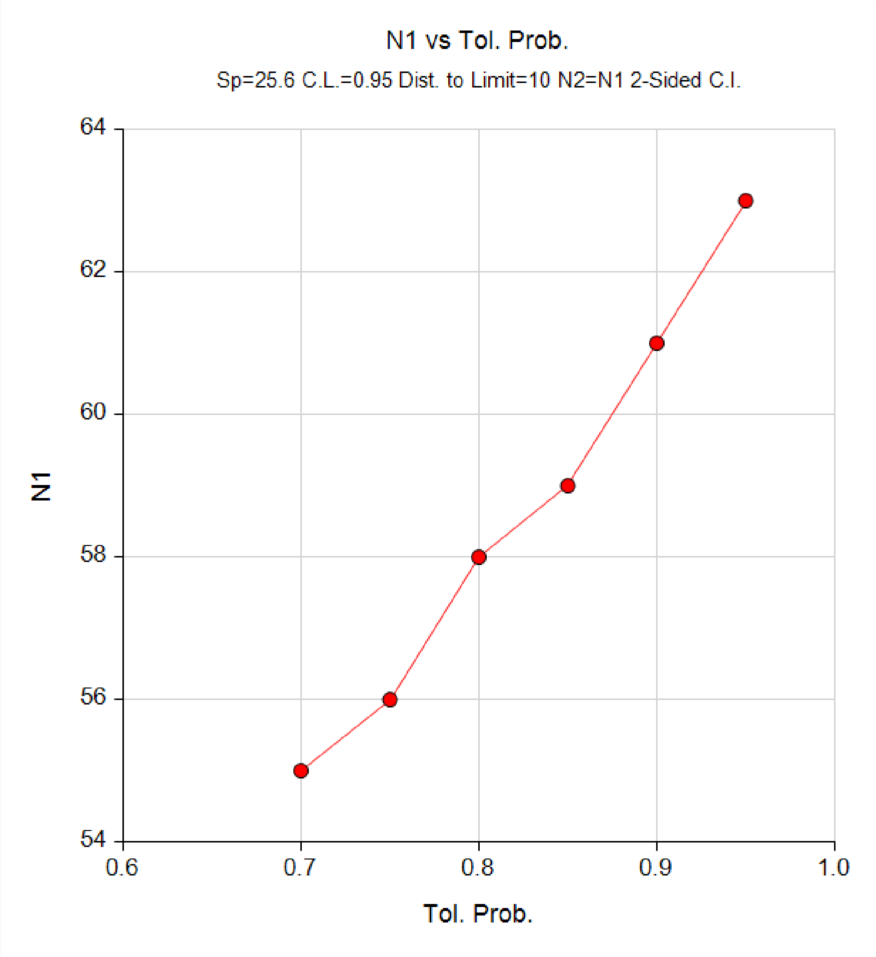
References

Kupper, L. L. and Hafner, K. B. 1989. 'How Appropriate are Popular Sample Size Formulas?', The American Statistician, Volume 43, No. 2, pp. 101-105.

This report shows the calculated sample size for each of the scenarios.

Plots Section

Plots



This plot shows the sample size of each group versus the precision for the two confidence levels.

Example 2 – Validation using Zar (1984)

Zar (1984) pages 133-134 gives an example of a precision calculation for a confidence interval for the difference between two means when the confidence level is 95%, the pooled standard deviation is 0.720625 from a total sample size of 13, the precision is 0.5, and the tolerance probability is 0.90. The sample size for each group is determined to be 34.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 2** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab

Solve For .... **Sample Size**
Interval Type .... **Two-Sided**
Confidence Level (1 - Alpha) **0.95**
Tolerance Probability **0.90**
Group Allocation .... **Equal (N1 = N2)**
Distance from Mean Difference to Limit(s)..... **0.5**
Standard Deviation Source .... **S from a Previous Sample**
S (SD Estimated from a Previous Sample) **0.720625**
Total Sample Size of Previous Sample.......... **13**

Output

Click the Calculate button to perform the calculations and generate the following output.

Numeric Results

Solve For: Sample Size
Interval Type: Two-Sided

Confidence Level	Sample Size N1	Sample Size N2	Sample Size N	Distance from Mean Difference to Limits Target	Distance from Mean Difference to Limits Actual	Pooled Standard Deviation	Tolerance Probability
0.95	34	34	68	0.5	0.496	0.72	0.9

Total sample size for estimate of pooled standard deviation from previous samples = 13.

PASS also calculated the sample size in each group to be 34.