Chapter 496

Confidence Intervals for Paired Means

Introduction

This routine calculates the sample size necessary to achieve a specified distance from the paired sample mean difference to the confidence limit(s) at a stated confidence level for a confidence interval about the mean difference when the underlying data distribution is normal.

Caution: This procedure assumes that the standard deviation of the future sample will be the same as the standard deviation that is specified. If the standard deviation to be used in the procedure is estimated from a previous paired sample or represents the population standard deviation, the Confidence Intervals for Paired Means with Tolerance Probability procedure should be considered. That procedure controls the probability that the distance from the mean paired difference to the confidence limits will be less than or equal to the value specified.

Technical Details

For a paired sample mean difference from a normal distribution with known variance, a two-sided, 100(1 – α)% confidence interval is calculated by

$$\bar{X}_{Diff} \pm \frac{z_{1-\alpha/2}\sigma_{Diff}}{\sqrt{n}}$$

where $\bar{X}_{Diff}$ is the mean of the paired differences of the sample, and σ_{Diff} is the known standard deviation of paired sample differences.

A one-sided 100(1 – α)% upper confidence limit is calculated by

$$\bar{X}_{Diff} + \frac{z_{1-\alpha}\sigma_{Diff}}{\sqrt{n}}$$

Similarly, the one-sided 100(1 – α)% lower confidence limit is

$$\bar{X}_{Diff} - \frac{z_{1-\alpha}\sigma_{Diff}}{\sqrt{n}}$$

For a paired sample mean difference from a normal distribution with unknown variance, a two-sided, 100(1 – α)% confidence interval is calculated by

$$\bar{X}_{Diff} \pm \frac{t_{1-\alpha/2,n-1}\hat{\sigma}_{Diff}}{\sqrt{n}}$$

where $\bar{X}_{Diff}$ is the mean of the paired differences of the sample, and $\hat{\sigma}_{Diff}$ is the estimated standard deviation of paired sample differences.

A one-sided 100(1 – α)% upper confidence limit is calculated by

$$\bar{X}_{Diff} + \frac{t_{1-\alpha,n-1}\hat{\sigma}_{Diff}}{\sqrt{n}}$$

Similarly, the one-sided 100(1 – α)% lower confidence limit is

$$\bar{X}_{Diff} - \frac{t_{1-\alpha,n-1}\hat{\sigma}_{Diff}}{\sqrt{n}}$$

Each confidence interval is calculated using an estimate of the mean difference plus and/or minus a quantity that represents the distance from the mean difference to the edge of the interval. For two-sided confidence intervals, this distance is sometimes called the precision, margin of error, or half-width. We will label this distance, *D*.

The basic equation for determining sample size when *D* has been specified is

$$D = \frac{z_{1-\alpha/2}\sigma_{Diff}}{\sqrt{n}}$$

when the standard deviation is known, and

$$D = \frac{t_{1-\alpha/2,n-1}\hat{\sigma}_{Diff}}{\sqrt{n}}$$

when the standard deviation is unknown. These equations can be solved for any of the unknown quantities in terms of the others. The value $\alpha/2$ is replaced by α when a one-sided interval is used.

Finite Population Size

The above calculations assume that samples are being drawn from a large (infinite) population. When the population is of finite size (*N*), an adjustment must be made. The adjustment reduces the standard deviation as follows:

$$\sigma_{finite} = \sigma\sqrt{1 - \frac{n}{N}}$$

This new standard deviation replaces the regular standard deviation in the above formulas.

The Standard Deviation of Paired Differences (σ_{Diff})

If you have results from a previous (or pilot) study, use the estimate of the standard deviation of paired differences, σ_{Diff}, from the study. Another reasonable (but somewhat rough) estimate of σ_{Diff} may be obtained using the range of paired differences as

$$\sigma_{Diff} = \frac{Range}{4}$$

If you have estimates of the expected standard deviations of the paired variables (σ_1 and σ_2) and the Pearson correlation between the paired variables (ρ), the standard deviation of paired differences (σ_{Diff}) may be calculated using the equation

$$\sigma_{Diff}^2 = \sigma_1^2 + \sigma_2^2 - 2\rho\sigma_1\sigma_2$$

such that

$$\sigma_{Diff} = \sqrt{\sigma_1^2 + \sigma_2^2 - 2\rho\sigma_1\sigma_2}\,.$$

If $\sigma_1 = \sigma_2 = \sigma_x$, then this formula reduces to

$$\sigma_{Diff}^2 = 2\sigma_x^2(1-\rho)$$

such that

$$\sigma_{Diff} = \sqrt{2\sigma_x^2(1-\rho)}\,.$$

If you have an estimate of the within-subject population standard deviation (σ_w), then σ_{Diff} may be calculated using the equation

$$\sigma_{Diff}^2 = 2\sigma_w^2$$

such that

$$\sigma_{Diff} = \sqrt{2\sigma_w^2}\,.$$

σ_w is often estimated by the square root of the within mean square error (WMSE) from a repeated measures ANOVA.

Confidence Level

The confidence level, 1 – α, has the following interpretation. If thousands of samples of n items are drawn from a population 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 – α.

Example 1 – Calculating Sample Size

A researcher would like to estimate the mean difference in weight following a specific diet using a two-sided 95% confidence interval. The confidence level is set at 0.95, but 0.99 is included for comparative purposes. The standard deviation estimate, based on the range of paired differences, is 9.6 lbs. The researcher would like the interval to be no wider than 10 lbs. (half-width = 5 lbs.), but will examine half-widths of 3, 4, 5, 6, and 7 lbs.

The goal is to determine the necessary sample size.

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**
Population Size .... **Infinite**
Confidence Level (1 - Alpha) **0.95 0.99**
Distance from Mean Difference to Limit(s)..... **3 to 7 by 1**
Standard Deviation Input Type .... **Enter the SD of Paired Differences**
S (SD of Paired Differences).......................... **9.6**
Known Standard Deviation .... **Unchecked**

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
Standard Deviation: Unknown

Confidence Level	Sample Size N	Distance from Mean Difference to Limits: Target	Distance from Mean Difference to Limits: Actual	Standard Deviation of Paired Differences S
0.95	42	3	2.99157	9.6
0.99	72	3	2.99458	9.6
0.95	25	4	3.96269	9.6
0.99	43	4	3.94993	9.6
0.95	17	5	4.93586	9.6
0.99	29	5	4.92600	9.6
0.95	13	6	5.80122	9.6
0.99	21	6	5.96068	9.6
0.95	10	7	6.86743	9.6
0.99	17	7	6.80058	9.6

Confidence Level	The proportion of confidence intervals (constructed with this same confidence level, sample size, etc.) that would contain the population mean difference.
N	The size of the sample (or number of pairs) drawn from the population.
Distance from Mean Difference to Limits	The distance from the confidence limit(s) to the mean paired difference. For two-sided intervals, it is also known as the precision, half-width, or margin of error.
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.
S	The standard deviation of paired differences for the population.

Summary Statements

A paired design will be used to obtain a two-sided 95% confidence interval for the paired mean difference. The standard t-distribution-based formula for the paired differences will be used to calculate the confidence interval. The estimated standard deviation of paired differences is assumed to be 9.6. To produce a confidence interval with a distance of no more than 3 from the paired sample mean difference to either limit, 42 pairs will be needed.

Dropout-Inflated Sample Size

Dropout Rate	Sample Size N	Dropout-Inflated Enrollment Sample Size N'	Expected Number of Dropouts D
20%	42	53	11
20%	72	90	18
20%	25	32	7
20%	43	54	11
20%	17	22	5
20%	29	37	8
20%	13	17	4
20%	21	27	6
20%	10	13	3
20%	17	22	5

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.
N The evaluable sample size at which the confidence interval is computed. If N subjects are evaluated out of the N' subjects that are enrolled in the study, the design will achieve the stated confidence interval.
N' The total number of subjects that should be enrolled in the study in order to obtain N evaluable subjects, based on the assumed dropout rate. After solving for N, N' is calculated by inflating N using the formula N' = N / (1 - DR), with N' 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.)
D The expected number of dropouts. D = N' - N.

Dropout Summary Statements

Anticipating a 20% dropout rate, 53 subjects should be enrolled to obtain a final sample size of 42 subjects.

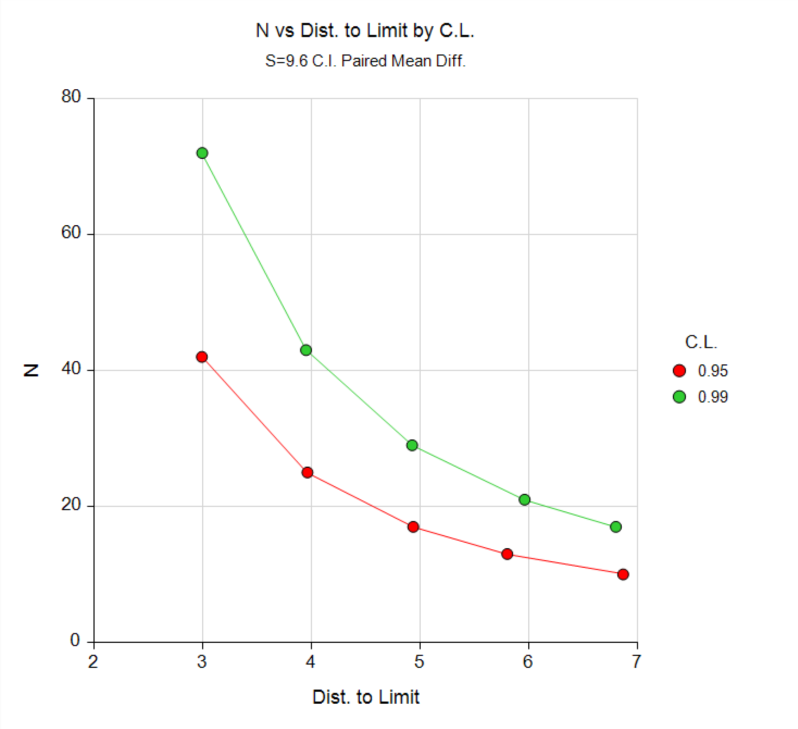
References

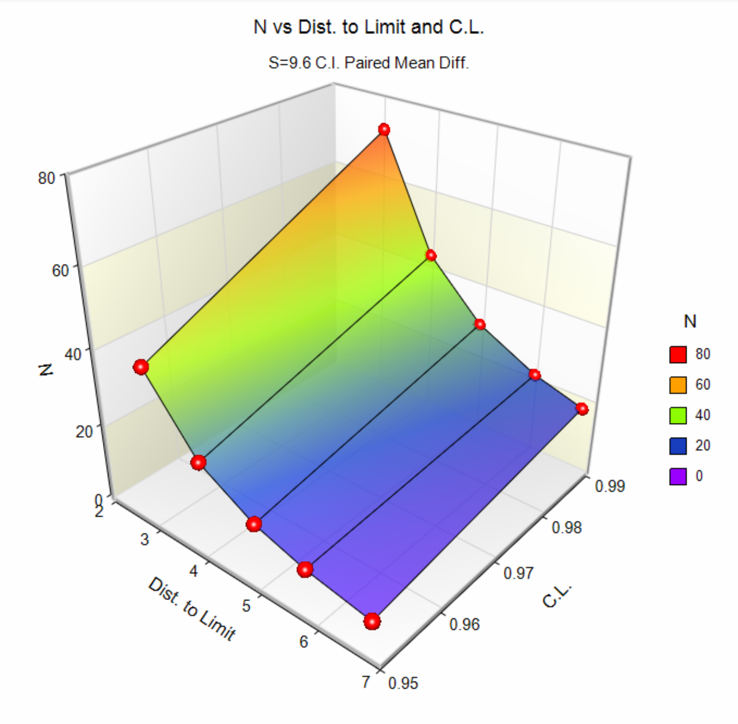
Hahn, G. J. and Meeker, W.Q. 1991. Statistical Intervals. John Wiley & Sons. New York.

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

Plots Section

Plots





These plots show the sample size versus the precision for the two confidence limits.

Example 2 – Validation

This procedure uses the same mechanics as the *Confidence Intervals for One Mean* procedure. The validation of this procedure is given in Examples 2 and 3 of the *Confidence Intervals for One Mean* procedure.