Chapter 744

Equivalence Tests for Simple Linear Regression

Introduction

This procedure computes power and sample size for equivalence tests of the slope in simple linear regression. Simple linear regression is a commonly used procedure in statistical analysis to model a linear relationship between a dependent variable Y and an independent variable X.

Difference between Simple Linear Regression and Correlation

The correlation coefficient is used when *X* and *Y* are from a bivariate normal distribution. That is, *X* is assumed to be a random variable whose distribution is normal. The values of X will not be known until the study is completed. In the simple linear regression context, no statement is made about the distribution of *X*. In fact, *X* does not have to be a random variable. In this procedure the distribution of Y is conditioned on X.

Fixed or Random X

Gatsonis and Sampson (1989) present power analysis results for two approaches: *unconditional* and *conditional*. This procedure provides a calculation for the *conditional* (fixed X) approach.

The *unconditional* approach assumes that X is normally distributed and is based on the correlation coefficient. The normality assumption might occasionally be met, but not frequently. Our impression is that usually, the values of X will not be known at the planning stage and they will not follow (even approximately) the normal distribution. Hence, the only option available is to proceed with the sample size calculation using the *conditional* approach and then estimate the standard deviation of the X's as best you can.

Technical Details

Suppose that the dependence of a variable *Y* on another variable *X* can be modeled using the simple linear equation

$$Y = A + BX$$

In this equation, *A* is the *Y*-intercept, *B* is the slope, *Y* is the dependent variable, and *X* is the independent variable.

The nature of the relationship between *Y* and *X* is studied using a sample of *N* observations. Each observation consists of a data pair: the *X* value and the *Y* value. The values of *A* and *B* are estimated from these observations using the method of least squares. Using these estimated values, each data pair may be modeled using the equation

$$Y_i = a + bX_i + e_i$$

Note that *a* and *b* are the least squares estimates of the population parameters *A* and *B*. The *e* values represent the discrepancies between the estimated values (*a* + *bX*) and the actual values *Y*. They are called the errors or residuals.

If it is assumed that these *e* values are normally distributed, tests of hypotheses about *A* and *B* can be constructed. Specifically, we can employ a pair of T-tests to test the equivalence of B compared to an interval defined by two equivalence limits, B_L and B_U.

The Statistical Hypotheses

PASS follows the two one-sided tests (TOST) approach for equivalence testing described by Schuirmann (1987) and power analysis using the bivariate, noncentral t distribution described by Phillips (1990). The bivariate, noncentral t is evaluated using the algorithm of Owen (1965).

Parameter	**Interpretation**	
B	*Population slope.*	This parameter will be estimated using the method of least squares.
B1	*Actual population slope at which power is calculated.*	
		This is the assumed population slope used in all calculations.
B_L, B_U	*Equivalence Limits.*	These are the boundaries of the slope between which the slope of the new group will still be considered equivalent to the reference slope.
B_R	*Reference value.*	This is the slope of the reference population.
EM	*Equivalence Margin.*	This is a tolerance value that defines the proportion of the slope that is not of practical importance. This may be thought of as the largest difference from the reference value that is still considered to be trivial.

Equivalence Tests

With $B_L < B_U$, the null hypothesis of non-equivalence is

$$H_0: B_R \leq B_L \ \text{ or } \ B_R \geq B_U.$$

The alternative hypothesis of equivalence is

$$H_1: B_L < B_R < B_U.$$

A pair of one-sample *t*-tests are used to analyze the data. The test assumes that the data are a simple random sample from a population of normally-distributed values that have the same variance. This assumption implies that the residuals are continuous and normal.

The calculation of the two, one-sided *t*-tests proceeds as follows

$$t_L = \frac{b - B_L}{s_b}$$

$$t_U = \frac{b - B_U}{s_b}$$

where s_b is the sample standard error of the regression coefficient. The test is usually calculated using a 100(1 – 2α)% confidence interval of the slope. If both limits of this confidence interval are between B_L and B_U, equivalence is concluded.

Power Calculation of the Equivalence Test of the Regression Coefficient, B

The power of this test is

$$\Pr\left(t_L \geq t_{1-\alpha,N-2} \text{ and } t_U \leq t_{\alpha,N-2} | \Delta_L, \Delta_U\right)$$

where t_L and t_U are distributed as the bivariate, noncentral *t* distribution with noncentrality parameters Δ_L and Δ_U given by

$$\Delta_L = \frac{B_R - B_L}{\sqrt{\sigma_e^2 / (\sigma_X^2 N)}}$$

$$\Delta_U = \frac{B_R - B_U}{\sqrt{\sigma_e^2 / (\sigma_X^2 N)}}.$$

The above probability is evaluated using the algorithm of Owen (1965) and Phillips (1990).

The sample size is found using a binary search with this power formula.

Calculation of σ_X

The above calculation requires the value of σ_X, the (population) standard deviation of the X values in the regression analysis. Except for the occasional experimental design that includes a specification of the X values (e.g., doses), the specific X values are unknown in the planning phase. Hence, a reasonable estimate must be found. PASS includes a special tool called the *Standard Deviation Estimator* that will aid in your search for accurate estimates of this parameter.

The following table provides examples of typical data configurations and their corresponding standard deviations.

σ_X	X Values	σ_X	X Values	σ_X	X Values	σ_X	X Values
0.500	1, 2	0.816	1, 2, 3	1.118	1, 2, 3, 4	1.414	1, 2, 3, 4, 5
1.000	1, 3	1.633	1, 3, 5	2.236	1, 3, 5, 7	2.828	1, 3, 5, 7, 9
1.500	1, 4	2.449	1, 4, 7	3.354	1, 4, 7, 10	4.243	1, 4, 7, 10, 13
2.000	1, 5	3.266	1, 5, 9	4.472	1, 5, 9, 13	5.657	1, 5, 9, 13, 17
4.000	1, 9	6.532	1, 9, 17	8.944	1, 9, 17, 25	11.314	1, 9, 17, 25, 33

Because of the direct impact on the power and sample size, it will be important to spend some time determining appropriate values for this parameter.

One final note: when a basic pattern is repeated, its population standard deviation remains the same. For example, the standard deviation of the values 1, 2, 1, 2, 1, 2is 0.5. This is also the standard deviation of 1, 2 or 1, 2, 1, 2.

Procedure Options

This section describes the options that are specific to this procedure. These are located on the Design tab. For more information about the options of other tabs, go to the Procedure Window chapter.

Design Tab

The Design tab contains most of the parameters and options that you will be concerned with.

Solve For

Solve For

This option specifies the parameter to be solved for from the other parameters. Under most situations, you will select either *Power* for a power analysis or *Sample Size* for sample size determination.

Select *Sample Size* when you want to calculate the sample size needed to achieve a given power and alpha level.

Select *Power* when you want to calculate the power of an experiment.

Power and Alpha

Power

This option specifies one or more values for power. Power is the probability of rejecting a false null hypothesis, and is equal to one minus Beta. Beta is the probability of a type-II error, which occurs when a false null hypothesis is not rejected.

Values must be between zero and one. Historically, the value of 0.80 (Beta = 0.20) was used for power. Now, 0.90 (Beta = 0.10) is commonly used.

A single value may be entered here or a range of values such as *0.8 to 0.95 by 0.05* may be entered.

Alpha

This option specifies one or more values for the probability of a type-I error (alpha). A type-I error occurs when you reject the null hypothesis when in fact it is true.

Values of alpha must be between zero and one. Historically, the value of 0.05 has been used for alpha. This means that about one test in twenty will falsely reject the null hypothesis. You should pick a value for alpha that represents the risk of a type-I error you are willing to take in your experimental situation.

You may enter a range of values such as *0.01 0.05 0.10* or *0.01 to 0.10 by 0.01*.

Sample Size

N (Sample Size)

Enter one or more values for the number of observations (e.g., subjects) in the study.

Effect Size – Slope

Equivalence Limit Input Type

Select the way you want to enter the equivalence limits.

Your options are

- **Upper and Lower Equivalence Limits**
  Enter the values of BL and BU directly.

- **Reference Slope, Equivalence Margin**
  Enter values for BR and Em. BL and BU will be determined from these values using BL = BR - |EM| and BU = BR + |EM|.

BU (Upper Equivalence Limit)

Enter one or more values of the upper equivalence limit of the slope. Slopes between BL and BU are assumed to be equivalent to the reference slope. Slopes outside these limits are non-equivalent.

You should make sure that BL < B1 < BU.

You can enter a single value such as '1' or a series of values such as '1 2 3' or '1 to 10 by 1'.

BL (Lower Equivalence Limit)

Enter one or more values of the lower equivalence limit of the slope. Slopes between BL and BU are assumed to be equivalent to the reference slope. Slopes outside these limits are non-equivalent.

You should make sure that BL < B1 < BU.

You can enter a single value such as '1' or a series of values such as '1 2 3' or '1 to 10 by 1'.

BR (Reference Slope)

Enter one or more values of the reference slope. This is the slope you are comparing the new slope against. This value is used with the equivalence margin (EM) to calculate the equivalence limits using the following

BL = BR - |EM|

BU = BR + |EM|

BR can be any numeric value.

You can enter a single value such as '1' or a series of values such as '1 2 3' or '1 to 10 by 1'.

EM (Equivalence Margin)

Enter one or more values of the equivalence margin, EM. This is the margin (tolerance) on either side of BR that you deem results in a slope that is equivalent. This value is used with the equivalence margin (EM) to calculate the equivalence limits using the following

BL = BR - |EM|

BU = BR + |EM|

EM can be any positive numeric value.

You can enter a single value such as '1' or a series of values such as '1 2 3' or '1 to 10 by 1".

B1 (Slope|H1)

Enter one or more values of the slope assumed by the alternative hypothesis, B1. This represents the actual value of B at which the power is computed.

You should make sure that BL < B1 < BU. You can enter a single value such as '1' or a series of values such as '1 2 3' or '1 to 10 by 1".

Effect Size – Standard Deviation of X

σx Input Type

Select the method you want to use to enter the value(s) of σx. Your choices are

- **σx (Std Dev of X)**
  Enter one or more values for σx directly.

- **List of X Values**
  Enter a list of two or more numbers from which the standard deviation is to be calculated.

σx (Standard Deviation of X)

Enter one or more values for σx, the *population* standard deviation of the X values that will occur in a sample.

Usually, the actual X values are not known at the planning stage. When they are not known, you will have to estimate this value. You can press the *Standard Deviation Estimator* button at the right to obtain help in determining appropriate values for this parameter. Just be sure to use the *population*, not the *sample*, formula. That is, divide the sum of squares by N, not N-1.

The individual numbers can be any numeric value: positive, negative, or zero.

Fixed Xs

Determine the standard deviation of a typical set of fixed Xs. For example, suppose the X values will be five -1's and five 1's. The population standard deviation of these values (dividing by N, not N - 1) is 1.0. This is the value of σx. Note that '1 2' will result in the same σx as '1 2 1 2', '1 1 1 2 2 2', '-1 -2', or '11 12'.

Random Xs

Estimate one or more values of σx, the standard deviation of X, from your knowledge of X. If nothing else is available, you can use the likely range divided by 4, 5, or 6.

List of X Values

Enter a list of values from which the value of σx will be calculated. For example, entering "1, 3" results in σx = 1.0. Note that this calculation assumes that the N observations are allocated equally among the X's.

Effect Size – σe (Standard Deviation of Residuals)

σe Input Type

Select the method to use to enter σe (the standard deviation of the residuals).

- **σe (Std Dev of Residuals)**
  Specify σe directly.

- **σY (Std Dev of Y)**
  Specify σY. Calculate: $\sigma e^2 = \sigma Y^2 - B1^2 (\sigma x^2)$

σe (Std Dev of Residuals)

Enter one or more values of the standard deviation of the residuals from the regression of Y on X. The possible range is $0 < \sigma e$.

σY (Std Dev of Y)

Enter one or more values for the standard deviation of Y, ignoring the independent variable X. The value of σY is converted to σe using the formula: $\sigma e^2 = \sigma Y^2 - B1^2 (\sigma x^2)$. The allowable range is $0 < |B1(\sigma x)| < \sigma Y$.

Example 1 – Calculating the Power

Suppose a power analysis is required for a simple linear regression study that will perform an equivalence test of the relationship between two variables, *Y* and *X*. Further suppose that in the past, the slope has been 1 and it will be advantageous to show that the slope of a new manufacturing process is similar. The equivalence limits are defined a 0.8 and 1.2.

The analysis will look at the power of several sample sizes between 300 and 1300. A significance level of 0.05 will be used. Based on previous studies, σe will be assumed to be 0.6. The value of σx will assume that X is binary with equally-likely values of 1 and 2. The power will be computed at B1 = 0.9, 0.95, and 1.

Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the **Equivalence Tests for Simple Linear Regression** procedure window. You may then make the appropriate entries as listed below, or open **Example 1** by going to the **File** menu and choosing **Open Example Template**.

Option	Value
Design Tab	
Solve For	**Power**
Alpha	**0.05**
N (Sample Size)	**300 500 700 900 1100 1300**
Equivalence Limit Input Type	**Upper and Lower Equivalence Limits**
B_U (Upper Equivalence Limit)	**1.2**
B_L (Lower Equivalence Limit)	**0.8**
B1 (Slope|H1)	**0.9 0.95 1**
σx Input Type	**List of X Values**
List of X Values	**1 2**
σe Input Type	**σe (Std Dev of Residuals)**
σe (Std Dev of Residuals)	**0.6**

Annotated Output

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

Numeric Results

Hypotheses: H0: $B \le B_L$ or $B \ge B_U$ vs. H1: $B_L < B < B_U$

Power	Sample Size N	Lower Equiv Limit B_L	Upper Equiv Limit B_U	Ref Slope B_R	Equiv Margin EM	Actual Slope B1	Std Dev of X σx	Std Dev of Y $σ_Y$	Std Dev of Resids σe	R^2	Alpha
0.4151	300	0.800	1.200	1.000	0.200	0.900	0.500	0.750	0.600	0.360	0.050
0.6716	300	0.800	1.200	1.000	0.200	0.950	0.500	0.765	0.600	0.385	0.050
0.7833	300	0.800	1.200	1.000	0.200	1.000	0.500	0.781	0.600	0.410	0.050
0.5855	500	0.800	1.200	1.000	0.200	0.900	0.500	0.750	0.600	0.360	0.050
0.8729	500	0.800	1.200	1.000	0.200	0.950	0.500	0.765	0.600	0.385	0.050
0.9622	500	0.800	1.200	1.000	0.200	1.000	0.500	0.781	0.600	0.410	0.050
0.7123	700	0.800	1.200	1.000	0.200	0.900	0.500	0.750	0.600	0.360	0.050
0.9516	700	0.800	1.200	1.000	0.200	0.950	0.500	0.765	0.600	0.385	0.050
0.9943	700	0.800	1.200	1.000	0.200	1.000	0.500	0.781	0.600	0.410	0.050
0.8037	900	0.800	1.200	1.000	0.200	0.900	0.500	0.750	0.600	0.360	0.050
0.9823	900	0.800	1.200	1.000	0.200	0.950	0.500	0.765	0.600	0.385	0.050
0.9992	900	0.800	1.200	1.000	0.200	1.000	0.500	0.781	0.600	0.410	0.050

(report continues)

References

Blackwelder, W.C. 1998. 'Equivalence Trials.' In Encyclopedia of Biostatistics, John Wiley and Sons. New York. Volume 2, 1367-1372.

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Owen, Donald B. 1965. 'A Special Case of a Bivariate Non-Central t-Distribution'. Biometrika, Volume 52, Pages 437-446.

Mathews, Paul. 2010. Sample Size Calculations - Practical Methods for Engineers and Scientists. Mathews Malnar and Bailey. Fairport Harbor, OH.

Dupont, W.D. and Plummer, W.D. Jr. 1998. 'Power and Sample Size Calculations for Studies Involving Linear Regression'. Controlled Clinical Trials, Vol. 19, Pages 589-601.

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Report Definitions

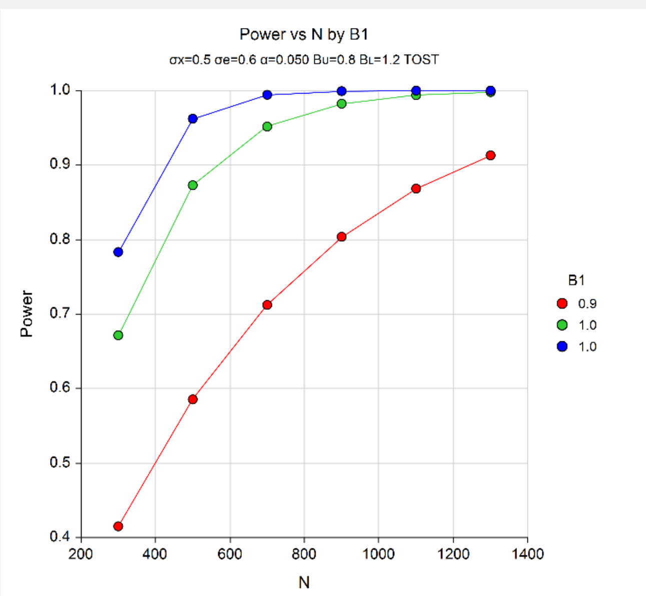
Power is the probability of rejecting a false null hypothesis. It should be close to one.
N is the size of the sample drawn from the population. To conserve resources, it should be small.
B_L is the lower equivalence limit of the slope.
B_U is the upper equivalence limit of the slope.
B_R is the reference (baseline or typical) slope.
EM is the equivalence margin. Note that EM = B_U - B_R = (B_U - B_L) / 2.
B1 is the slope at which the power is calculated.
σ_X is the standard deviation of the X values.
σ_Y is the standard deviation of Y (ignoring X).
σ_e is the standard deviation of the residuals.
R^2 is the R-squared when Y is regressed on X.
Alpha is the probability of rejecting a true null hypothesis.

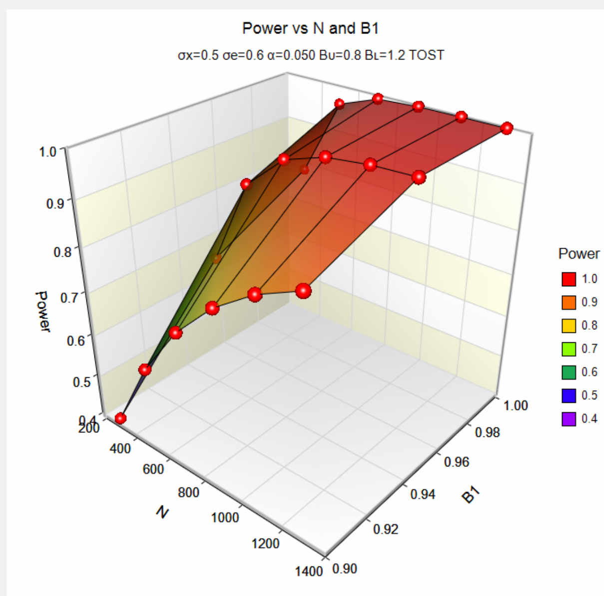
Summary Statements

An equivalence test is planned. A sample size of 300 achieves 42% power to detect the equivalence of a slope of 0.900 under the alternative hypothesis when the lower and upper equivalence limits are 0.800 and 1.200, the equivalence margin is 0.200, the reference slope is 1.000, the significance level is 0.050, the standard deviation of X is 0.500, the standard deviation of Y is 0.750, the standard deviation of residuals is 0.600, and R^2 is 0.360.

This report shows the calculated power for each of the scenarios.

Plots Section





These plots show the power versus the sample size for the three values of B1.

Example 2 – Validation using Another PASS Procedure

We could not find a validation example for this procedure in the literature. But since this procedure can be derived from the **One-Sample T-Tests for Equivalence** procedure, we will use an example from that previously validated procedure to validate this procedure.

In the other procedure, set the *Solve For* parameter to Sample Size. Also, set $Power = 0.9, EU = 1.2, EL = 0.8, \mu 1 = 0.9\ 0.95\ 1, \alpha = 0.05,$ and $\sigma = 0.6$.

The sample sizes are 310, 139, and 99.

Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the **Equivalence Tests for Simple Linear Regression** procedure window. You may then make the appropriate entries as listed below, or open **Example 2** by going to the **File** menu and choosing **Open Example Template**.

Option	Value
Design Tab	
Solve For	**Sample Size**
Power	**0.9**
Alpha	**0.05**
Equivalence Limit Input Type	**Upper and Lower Equivalence Limits**
BU (Upper Equivalence Limit)	**1.2**
BL (Lower Equivalence Limit)	**0.8**
B1 (Slope|H1)	**0.9 0.95 1**
σx Input Type	**σx (Std Dev of X)**
σx (Std Dev of X)	**1**
σe Input Type	**σe (Std Dev of Residuals)**
σe (Std Dev of Residuals)	**0.6**

Output

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

Numeric Results
Hypotheses: H0: B ≤ BL or B ≥ BU vs. H1: BL < B < BU

Power	Sample Size N	Lower Equiv Limit BL	Upper Equiv Limit BU	Ref Slope BR	Equiv Margin EM	Actual Slope B1	Std Dev of X σx	Std Dev of Y σY	Std Dev of Resids σe	R^2	Alpha
0.9003	310	0.800	1.200	1.000	0.200	0.900	1.000	1.082	0.600	0.692	0.050
0.9005	139	0.800	1.200	1.000	0.200	0.950	1.000	1.124	0.600	0.715	0.050
0.9008	99	0.800	1.200	1.000	0.200	1.000	1.000	1.166	0.600	0.735	0.050

The sample sizes of 310, 139, and 99 match the results from the other procedure.