

Chapter 165

Equivalence Tests for the Difference Between Two Correlated Proportions

Introduction

The procedure described in this chapter compute power and sample size for testing equivalence using differences in designs in which two dichotomous responses are measured on each subject.

When one is interested in showing that two correlated proportions are different, the data are often analyzed with McNemar's test. However, the procedures discussed here are interested in showing equivalence rather than difference. For example, suppose a diagnostic procedure is accurate, but is expensive to apply or has serious side effects. A replacement procedure may be sought which is equally accurate, but is less expensive or has fewer side effects. In this case, we are not interested in showing that the two diagnostic procedures are different, but rather that they are the same. Equivalence tests were designed for this situation.

These tests are often divided into two categories: *equivalence* (two-sided) tests and *non-inferiority* (one-sided) tests. Here, the term *equivalence tests* means that we want to show that two diagnostic procedures are equivalent—that is, their accuracy is about the same. This requires a two-sided hypothesis test. On the other hand, *non-inferiority tests* are used when we want to show that a new (experimental) procedure is no worse than the existing (reference or gold-standard) one. This requires a one-sided hypothesis test.

Technical Details

The results of a study in which two dichotomous responses are measured on each subject can be displayed in a 2-by-2 table in which one response is shown across the columns and the other is shown down the rows. In the discussion to follow, the columns of the table represent the standard (reference or control) response and the rows represent the treatment (experimental) response. The outcome probabilities can be classified into the following table.

Experimental Diagnosis	Standard Yes	Diagnosis No	Total
Yes	p_{11}	p_{10}	P_T
No	p_{01}	p_{00}	$1 - P_T$
Total	P_S	$1 - P_S$	1

In this table, $p_{ij} = p_{Treatment, Standard}$. That is, the first subscript represents the response of the new, experimental procedure while the second subscript represents the response of the standard procedure. Thus, p_{01} represents the proportion having a negative treatment response and a positive standard response.

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Sensitivity, Specificity, and Prevalence

To aid in interpretation, analysts have developed a few proportions that summarize the table. Three of the most popular ratios are *sensitivity*, *specificity*, and *prevalence*.

Sensitivity

Sensitivity is the proportion of subjects with a positive standard response who also have a positive experimental response. In terms of proportions from the 2-by-2 table,

$$\text{Sensitivity} = p_{11} / (p_{01} + p_{11}) = p_{11} / P_S$$

Specificity

Specificity is the proportion of subjects with a negative standard response who also have a negative experimental response. In terms of proportions from the 2-by-2 table,

$$\text{Specificity} = p_{00} / (p_{10} + p_{00})$$

Prevalence

Prevalence is the overall proportion of individuals with the disease (or feature of interest). In terms of proportions from the 2-by-2 table,

$$\text{Prevalence} = P_S$$

Table Probabilities

The outcome counts from a sample of n subjects can be classified into the following table.

Experimental Diagnosis	Standard Diagnosis		Total
	Yes	No	
Yes	n_{11}	n_{10}	n_T
No	n_{01}	n_{00}	$n - n_T$
Total	n_S	$n - n_S$	n

Note that $n_{11} + n_{00}$ is the number of matches (*concordant pairs*) and $n_{10} + n_{01}$ is the number of *discordant pairs*.

The hypothesis of interest concerns the two marginal probabilities P_T and P_S . P_S represents the accuracy or success of the standard test and P_T represents the accuracy or success of the new, experimental test. Equivalence is defined in terms of either the difference, $D = P_T - P_S$, or the relative risk ratio, $R = P_T / P_S$, of these two proportions. The choice between D and R will usually lead to different sample sizes to achieve the same power.

Equivalence Hypotheses using Differences

This section is based on Liu, Hsueh, Hsieh and Chen (2002). We refer you to that paper for complete details.

The hypotheses of equivalence in terms of the difference are

$$H_0: P_T - P_S \geq D_E \quad \text{or} \quad H_0: P_T - P_S \leq -D_E \quad \text{versus} \quad H_1: -D_E < P_T - P_S < D_E$$

These hypotheses can be decomposed into two sets of one-sided hypotheses

$$H_{0L}: P_T - P_S \leq -D_E \quad \text{versus} \quad H_{1L}: P_T - P_S > -D_E$$

and

$$H_{0U}: P_T - P_S \geq D_E \quad \text{versus} \quad H_{1U}: P_T - P_S < D_E$$

The hypothesis test of equivalence with type I error rate α is conducted by computing a $100(1 - 2\alpha)\%$ confidence interval for $P_T - P_S$ and determining if this interval is wholly contained between $-D_E$ and D_E . This confidence interval approach is often recommended by regulatory agencies.

Liu et al. (2002) discuss the RMLE-based (score) method for constructing these confidence intervals. This method is based on (developed by, described by) Nam (1997).

Asymptotic Tests

An asymptotic test for testing H_{0L} versus H_{1L} is given by

$$Z_L = \frac{\hat{D} + D_E}{\hat{\sigma}} = \frac{c + nD_E}{\sqrt{d - n\hat{D}^2}} \geq z_\alpha$$

where

$$\hat{D} = \frac{n_T}{n} - \frac{n_S}{n} = \frac{n_{10}}{n} - \frac{n_{01}}{n}$$

$$d = n_{10} + n_{01}$$

$$c = n_{10} - n_{01}$$

and z_α is the standard normal deviate having α in the right tail.

Similarly, an asymptotic test for testing H_{0U} versus H_{1U} is given by

$$Z_U = \frac{\hat{D} - D_E}{\hat{\sigma}} = \frac{c - nD_E}{\sqrt{d - n\hat{D}^2}} \leq -z_\alpha.$$

Equivalence is concluded if both the tests on Z_L and Z_U are rejected.

An estimate of $\hat{\sigma}$ based on the RMLE-based (score) procedure of Nam (1997) uses the estimates

$$\tilde{\sigma}_L = \sqrt{\frac{\tilde{p}_{L,10} + \tilde{p}_{L,01} - D_E^2}{n}}$$

and

$$\tilde{\sigma}_U = \sqrt{\frac{\tilde{p}_{U,10} + \tilde{p}_{U,01} - D_E^2}{n}}$$

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where

$$\tilde{p}_{L,10} = \frac{-\tilde{a}_L + \sqrt{\tilde{a}_L^2 - 8\tilde{b}_L}}{4}$$

$$\tilde{p}_{L,01} = \tilde{p}_{L,10} - D_E$$

$$\tilde{p}_{U,10} = \frac{-\tilde{a}_U + \sqrt{\tilde{a}_U^2 - 8\tilde{b}_U}}{4}$$

$$\tilde{p}_{U,01} = \tilde{p}_{U,10} + D_E$$

$$\tilde{a}_{L,01} = -\hat{D}(1 - D_E) - 2(\hat{p}_{01} + D_E)$$

$$\tilde{b}_{L,01} = D_E(1 + D_E)\hat{p}_{01}$$

$$\tilde{a}_{U,01} = -\hat{D}(1 + D_E) - 2(\hat{p}_{01} - D_E)$$

$$\tilde{b}_{U,01} = -D_E(1 - D_E)\hat{p}_{01}$$

Note that the ICH E9 guideline (see Lewis (1999)) suggests using a significance level of $\alpha / 2$ when testing this hypothesis.

Power Formula

The power when the actual difference is D_A can be evaluated exactly using the multinomial distribution. However, when the sample size is above a user-set level, we use a normal approximation to this distribution which leads to

$$1 - \beta(D_A) = \begin{cases} \Phi(c_U) - \Phi(c_L) & \text{if } c_U - c_L > 0 \\ 0 & \text{otherwise} \end{cases}$$

where

$$c_U = \frac{-D_A}{\sigma} + \frac{D_E}{\sigma} - \frac{z_\alpha}{w_U}$$

$$c_L = \frac{-D_A}{\sigma} - \frac{D_E}{\sigma} + \frac{z_\alpha}{w_L}$$

$$\sigma = \sqrt{\frac{p_{01} + p_{10} - D_A^2}{n}}$$

$$w_L = \sqrt{\frac{2p_{01} + D_A - D_A^2}{2\tilde{p}_{L,01} - D_E - D_E^2}}$$

$$w_U = \sqrt{\frac{2p_{01} + D_A - D_A^2}{2\tilde{p}_{U,01} + D_E - D_E^2}}$$

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$$\bar{p}_{L,01} = \frac{-a_L + \sqrt{a_L^2 - 8b_L}}{4}$$

$$\bar{p}_{U,01} = \frac{-a_U + \sqrt{a_U^2 - 8b_U}}{4}$$

$$a_L = -D_A(1 - D_E) - 2(p_{01} + D_E)$$

$$b_L = D_E(1 + D_E)p_{01}$$

$$a_U = -D_A(1 + D_E) - 2(p_{01} - D_E)$$

$$b_U = -D_E(1 - D_E)p_{01}$$

Nuisance Parameter

Unfortunately, the 2-by-2 table includes four parameters p_{11} , p_{10} , p_{01} , and p_{00} , but the power specifications above only specify two parameters: P_S and D_A or R_A . A third parameter is defined implicitly since the sum of the four parameters is one. One parameter, known as a nuisance parameter, remains unaccounted for. This parameter must be addressed to fully specify the problem. This fourth parameter can be specified by specifying any one of the following: p_{11} , p_{10} , p_{01} , p_{00} , $p_{10} + p_{01}$, $p_{11} + p_{00}$, or the sensitivity of the experimental response, p_{11} / P_S .

It may be difficult to specify a reasonable value for the nuisance parameter since its value may not be even approximately known until after the study is conducted. Because of this, we suggest that you calculate power or sample size for a range of values of the nuisance parameter. This will allow you to determine how sensitive the results are to its value.

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 the parameters associated with this test such as the proportions, sample sizes, alpha, and power.

Solve For

Solve For

This option specifies the parameter to be solved for from the other parameters. The parameters that may be selected are *Power* or *Sample Size*.

Equivalence Tests for the Difference Between Two Correlated Proportions

Power Calculation

Power Calculation Method

Select the method to be used to calculate power.

The choices are

- **Multinomial Enumeration**

Power is computed using multinomial enumeration of all possible outcomes when $N \leq \text{Max } N$ for Multinomial Enumeration (otherwise, the normal approximation is used). Multinomial enumeration of all outcomes is possible because of the discrete nature of the data.

- **Normal Approximation**

Approximate power is computed using the normal approximation to the multinomial distribution.

The exact calculation using the multinomial distribution becomes very time consuming for $N > 500$. When $N > 500$, the difference between the multinomial and approximate calculations is small.

For small values of N (less than 100), the Multinomial Enumeration power may be overly optimistic because the discrete nature of the trinomial distribution results in the actual alpha value being higher than its target. To be on the safe side, we recommend that you use the approximate calculation.

Max N for Multinomial Enumeration

Only shown when Power Calculation Method = "Multinomial Enumeration"

Specify the maximum value of N (sample size) that uses the exact power calculation based on the multinomial distribution. N 's greater than this value will use the asymptotic approximation.

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 you fail to conclude equivalence when in fact it is true.

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 also 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. A type-I error occurs when a true null hypothesis is rejected. Here, a type-I error occurs when you falsely conclude equivalence.

Sample Size

N (Sample Size)

Enter a value for the sample size. This value must be greater than two. You may enter a range of values such as *10 to 100 by 10*.

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Effect Size – Differences

|De| (Equivalence Difference)

|De| is the maximum allowable difference between the standard and treatment proportions that will still result in the conclusion of equivalence.

Only positive values can be entered here. Typical values for this difference are 0.05, 0.10, and 0.20. For 2-sided tests, you must have $|Da| < |De|$.

Da (Actual Difference)

Enter Da, the actual difference between the standard and treatment proportions ($P_t - P_s$). This value is used to generate the value of P_t using the formula $P_t = P_s + Da$.

Often this value is set equal to zero, but this is not necessary. For 2-sided tests, you must have $|Da| < |De|$.

Effect Size – Standard Proportion

Ps (Standard Proportion)

This is the proportion of yes's (or successes), P_s , when subjects received the standard treatment. This value or a good estimate is often available from previous studies.

Note that this value does not matter when the Nuisance Parameter Type is set to "P01" (or "P10"), as long as it is greater than P01 (or P10).

You may enter a set of values separated by blank spaces. For example, you could enter *0.50 0.60 0.70*. Values between, but not including, 0 and 1 are permitted.

Effect Size – Nuisance Parameter

Nuisance Parameter Type

Enter the type of nuisance parameter here. Unfortunately, the 2-by-2 table cannot be completely specified by using only the parameters P_s and Da or P_s and R_a . One other parameter must be specified. This additional parameter is called a "nuisance" parameter. It will be assumed to be a known quantity. Several possible choices are available. This option lets you specify which parameter you want to use. In all cases, the value you specify is a proportion.

- **P11 (% Positive Matches)**
The proportion of subjects that are positive on both tests.
- **P00 (% Negative Matches)**
The proportion of subjects that are negative on both tests.
- **P01 (% -Trt +Std)**
The proportion of subjects that are negative on the treatment, but positive on the standard.
- **P10 (% +Trt -Std)**
The proportion of subjects that are positive on the treatment, but negative on the standard.
- **P11+P00 (% Matches)**
The proportion of matches (concordant pairs).
- **P01+P10 (% Disagree)**
The proportion of non-matches (discordant pairs).

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- **P11/Ps (Sensitivity)**

The sensitivity.

Nuisance Parameter Value

Enter the value of the nuisance parameter that you specified in the “Nuisance Parameter Type” box. This value is a proportion, so it must be between 0 and 1.

Example 1 – Finding Power

A clinical trial will be conducted to show that a non-invasive MRI test is equivalent to the invasive CTAP reference test. Historical data suggest that the CTAP test is 80% accurate. After careful discussion, the researchers decide that if the MRI test is within five percentage points of the CTAP, it will be considered equivalent. They decide to use a difference test statistic. Thus, the equivalence difference is 0.05. They want to study the power for various sample sizes between 200 and 1000 at the 5% significance level.

They use P01 as the nuisance parameter and look at two values: 0.05 and 0.10.

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 the Difference Between Two Correlated Proportions** procedure window by expanding **Proportions**, then **Two Correlated Proportions**, then clicking on **Non-Inferiority**, and then clicking on **Equivalence Tests for the Difference Between Two Correlated Proportions**. 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**.

<u>Option</u>	<u>Value</u>
Design Tab	
Solve For	Power
Power Calculation Method.....	Normal Approximation
Alpha.....	0.05
N (Sample Size).....	200 300 450 600 800 1000
De (Equivalence Difference).....	0.05
Da (Actual Difference)	0.0
Ps (Standard Proportion)	0.80
Nuisance Parameter Type	P01 (% -Trt +Std)
Nuisance Parameter Value.....	0.05 0.10

Annotated Output

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

Numeric Results

Numeric Results for an Equivalence (Two-Sided) Test of a Difference

Power	Sample Size N	Equiv. Difference De	Actual Difference Da	Treatment Proportion Pt	Standard Proportion Ps	Nuisance Parameter P01	Alpha
0.35542	200	0.050	0.000	0.800	0.800	0.050	0.050
0.00000	200	0.050	0.000	0.800	0.800	0.100	0.050
0.66488	300	0.050	0.000	0.800	0.800	0.050	0.050
0.20739	300	0.050	0.000	0.800	0.800	0.100	0.050
0.88574	450	0.050	0.000	0.800	0.800	0.050	0.050
0.51491	450	0.050	0.000	0.800	0.800	0.100	0.050

(report continues)

* Power was computed using the normal approximation method.

Report Definitions

Power is the probability of rejecting a false null hypothesis.

N is the number of subjects, the sample size.

|De| is the maximum difference between the two proportions that is still called 'equivalent.'

Da is the actual difference between Pt and Ps. That is, $Da = Pt - Ps$.

Pt is the response proportion to the treatment (experimental or new) test.

Ps is the response proportion to the standard (reference or old) test.

The Nuisance Parameter is a value that is needed, but is not a direct part of the hypothesis.

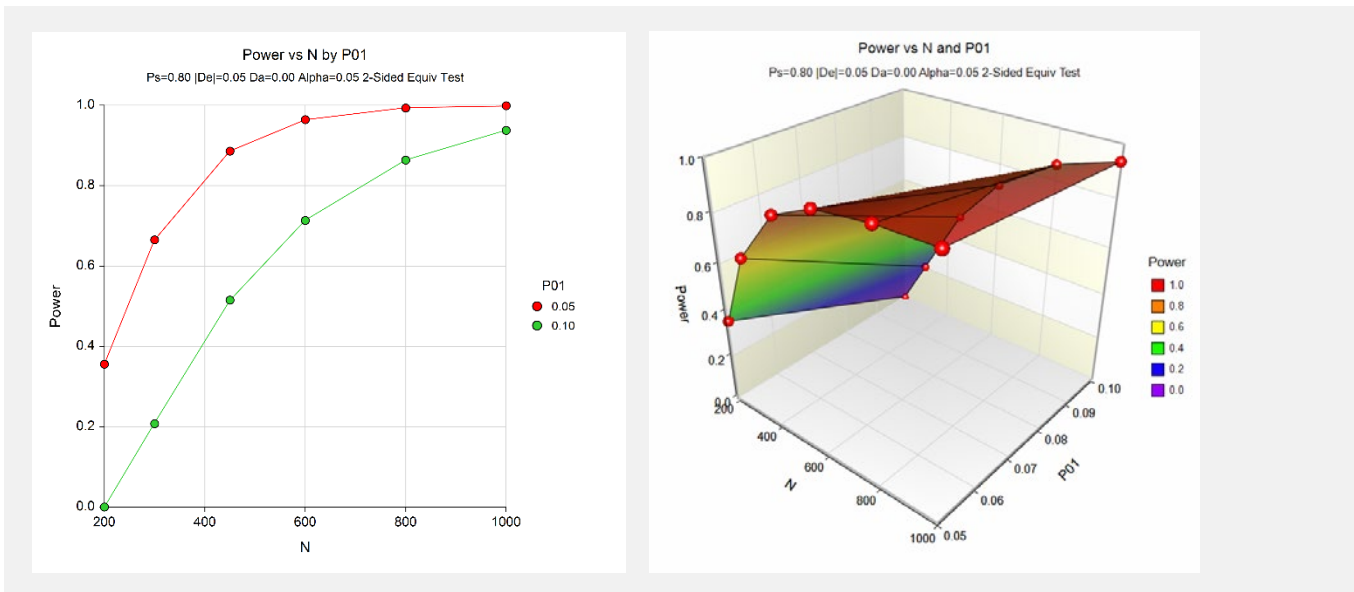
Alpha is the probability of rejecting a true null hypothesis.

Summary Statements

A sample size of 200 subjects achieves 35.542% power at a significance level of 0.050 using a two-sided equivalence test of correlated proportions when the standard proportion is 0.800, the maximum allowable difference between these proportions that still results in equivalence (the range of equivalence) is 0.050, and the actual difference of the proportions is 0.000.

This report shows the power for the indicated scenarios. All of the columns are defined in the “Report Definitions” section.

Plots Section



These plots show the power versus the sample size for the two values of P01. In this example, we see that the value of the nuisance parameter has a large effect on the calculated sample size.

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Example 2 – Finding Sample Size

Continuing with Example 1, the analysts want to determine the exact sample size necessary to achieve 90% power for both values of the nuisance parameter.

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 the Difference Between Two Correlated Proportions** procedure window by expanding **Proportions**, then **Two Correlated Proportions**, then clicking on **Non-Inferiority**, and then clicking on **Equivalence Tests for the Difference Between Two Correlated Proportions**. 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**.

<u>Option</u>	<u>Value</u>
Design Tab	
Solve For	Sample Size
Power Calculation Method.....	Normal Approximation
Power.....	0.90
Alpha.....	0.05
De (Equivalence Difference).....	0.05
Da (Actual Difference)	0.0
Ps (Standard Proportion)	0.80
Nuisance Parameter Type.....	P01 (% -Trt +Std)
Nuisance Parameter Value.....	0.05 0.10

Output

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

Numeric Results

Numeric Results for an Equivalence (Two-Sided) Test of a Difference							
Power	Sample Size N	Equiv. Difference De	Actual Difference Da	Treatment Proportion Pt	Standard Proportion Ps	Nuisance Parameter P01	Alpha
0.90019	468	0.050	0.000	0.800	0.800	0.050	0.050
0.90002	881	0.050	0.000	0.800	0.800	0.100	0.050
* Power was computed using the normal approximation method.							

This report shows that the sample size required nearly doubles when P01 is changed from 0.05 to 0.10.

Example 3 – Finding Power Following an Experiment

An experiment involving a single group of 57 subjects was run to show that a new treatment was equivalent to a previously used standard. Historically, the standard treatment has had a 48% success rate. The new treatment is known to have similar side effects to the standard, but is much less expensive. The treatments were to be considered equivalent if the success rate of the new treatment is within 10% of the success rate of the standard.

To compare the new and standard treatments, each of the 57 subjects received both treatments with a washout period between them. Thus, the proportions based on the two treatments are correlated. Of the 57 subjects, 18 responded to both treatments, 20 did not respond to either treatment, 9 responded to the new treatment but not the standard, and 10 responded to the standard but not the new treatment. The proportion responding to the new treatment is $(18+9)/57 = 0.4737$. The proportion responding to the standard is $(18+10)/57 = 0.4912$. The difference is 0.0175, lower than the threshold for equivalence, but the resulting p-value was 0.3358, indicating the two treatments could not be deemed equivalent at the 0.05 level. Note that McNemar's test only uses the discordant pairs, so the effective size of this study is really only $9 + 10 = 19$, although 57 subjects were investigated. The researchers want to know the power of the test they used.

It may be the inclination of the researchers to use the observed difference in proportions for calculating power. The p-value, however, is based on the maximum allowable difference for equivalence, which is 10% of 0.48, or 0.048. This is the number that should be used in the power calculation. The experiment gave a value of $P01$ of $10/28 = 0.36$. The power of the experiment is near zero for all values of $P01$ less than 0.10. We calculate the power for a variety of nuisance parameter values ($P01 = 0.01, 0.03, 0.05, \text{ and } 0.10$) to monitor its effect. Because it is in fact believed that the success rates are equivalent for the two treatments, the specified actual difference is set to 0.

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 the Difference Between Two Correlated Proportions** procedure window by expanding **Proportions**, then **Two Correlated Proportions**, then clicking on **Non-Inferiority**, and then clicking on **Equivalence Tests for the Difference Between Two Correlated Proportions**. You may then make the appropriate entries as listed below, or open **Example 3** by going to the **File** menu and choosing **Open Example Template**.

<u>Option</u>	<u>Value</u>
Design Tab	
Solve For	Power
Power Calculation Method.....	Multinomial Enumeration
Max N for Multinomial Enumeration	1000
Alpha.....	0.05
N (Sample Size).....	57
De (Equivalence Difference).....	0.048
Da (Actual Difference)	0.0
Ps (Standard Proportion).....	0.48
Nuisance Parameter Type.....	P01 (% -Trt +Std)
Nuisance Parameter Value.....	0.01 0.03 0.05 0.10

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Output

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

Numeric Results

Numeric Results for an Equivalence (Two-Sided) Test of a Difference								
	Sample Size	Equiv. Difference	Actual Difference	Treatment Proportion	Standard Proportion	Nuisance Parameter		
Power	N	De	Da	Pt	Ps	P01	Alpha	
0.31614	57	0.048	0.000	0.480	0.480	0.010	0.050	
0.02940	57	0.048	0.000	0.480	0.480	0.030	0.050	
0.00247	57	0.048	0.000	0.480	0.480	0.050	0.050	
0.00000	57	0.048	0.000	0.480	0.480	0.100	0.050	

* Power was computed using multinomial enumeration of all possible outcomes.

Note that there is no power for value of P01 greater than 0.05. This is probably due to the low number of discordant pairs.

Example 4 – Validation using Liu et al. (2002)

Liu *et al.* (2002) page 238 give a table of power values calculated by multinomial enumeration for sample sizes of 50, 100, and 200 when the significance level is 0.05. From this table, we find that when P01 is 0.10, P10 is 0.10, Da = P01 - P10 = 0.00, and De is 0.10, and the three power values are 0.026, 0.417, and 0.861 for the column head “RMLE-based Without CC” (this is the case we use).

In their calculations, they round the z value to 1.64. This corresponds to an alpha value of 0.0505025835. So that our results match, we will use this value for alpha rather than 0.05. In this example, the value of Ps is not used.

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 the Difference Between Two Correlated Proportions** procedure window by expanding **Proportions**, then **Two Correlated Proportions**, then clicking on **Non-Inferiority**, and then clicking on **Equivalence Tests for the Difference Between Two Correlated Proportions**. You may then make the appropriate entries as listed below, or open **Example 4** by going to the **File** menu and choosing **Open Example Template**.

<u>Option</u>	<u>Value</u>
Design Tab	
Solve For	Power
Power Calculation Method.....	Multinomial Enumeration
Max N for Multinomial Enumeration	1000
Alpha.....	0.0505025835
N (Sample Size).....	50 100 200
De (Equivalence Difference).....	0.1
Da (Actual Difference)	0.0
Ps (Standard Proportion)	0.5
Nuisance Parameter Type.....	P01 (% -Trt +Std)
Nuisance Parameter Value.....	0.1

Equivalence Tests for the Difference Between Two Correlated Proportions

Output

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

Numeric Results

Numeric Results for an Equivalence (Two-Sided) Test of a Difference

Power	Sample Size N	Equiv. Difference De	Actual Difference Da	Treatment Proportion Pt	Standard Proportion Ps	Nuisance Parameter P01	Alpha
0.02614	50	0.100	0.000	0.500	0.500	0.100	0.051
0.41741	100	0.100	0.000	0.500	0.500	0.100	0.051
0.86080	200	0.100	0.000	0.500	0.500	0.100	0.051

* Power was computed using multinomial enumeration of all possible outcomes.

As you can see, the values computed by **PASS** match the results of Liu et al. (2002).