

Chapter 150

Tests for Two Correlated Proportions (McNemar Test)

Introduction

McNemar's test compares the proportions for two correlated dichotomous variables. These two variables may be two responses on a single individual or two responses from a matched pair (as in matched case-control studies).

This procedure is similar to the Matched Case-Control procedure also available in **PASS**. It differs from that procedure in three basic ways:

1. The results may be calculated exactly by multinomial enumeration using an unconditional formula rather than using conditional, normal approximations.
2. It only deals with the case of a matched pair: one case and one control (the Matched Case-Control procedure lets you match several controls with each case).
3. It is based directly on a 2-by-2 contingency table.

To fix these ideas, consider the following fictitious data concerning the relationship between smoking and lung cancer. Suppose that a sample of $N = 100$ cases of identical twins in which only one twin has lung cancer is selected for further study. The twin with lung cancer is the *case*. The other twin serves as the *control*. Each pair of twins is surveyed to determine if they smoke tobacco. The results are summarized in the following two-way table:

	<u>No Lung Cancer Twin (Control)</u>	
<u>Lung Cancer Twin (Case)</u>	<u>Smokes = Yes</u>	<u>Smokes = No</u>
Smokes = Yes	16	21
Smokes = No	4	59

There is a basic difference between this table and the more common two-way table. In the matched-paired case, the count represents the number of pairs, not the number of individuals.

The investigator wishes to compare the proportion of cases that smoke with the proportion of controls that smoke. The proportion of controls who smoke is $(16+4)/100 = 0.20$. The proportion of cases who smoke is $(16+21)/100 = 0.37$.

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Dividing each of the entries in the table by N gives the proportions:

		<u>No Lung Cancer Twin (Control)</u>		
<u>Lung Cancer Twin (Case)</u>		<u>Smokes = Yes</u>	<u>Smokes = No</u>	<u>Total</u>
<u>Smokes = Yes</u>		0.16	0.21	0.37
<u>Smokes = No</u>		0.04	0.59	0.63
<u>Total</u>		0.20	0.80	0.63

Symbolically, this table is represented as:

		<u>No Lung Cancer Twin (Control)</u>		
<u>Lung Cancer Twin (Case)</u>		<u>Smokes = Yes</u>	<u>Smokes = No</u>	<u>Total</u>
<u>Smokes = Yes</u>		P11	P10	Pt
<u>Smokes = No</u>		P01	P00	1-Pt
<u>Total</u>		Ps	1-Ps	1

Formally, the hypothesis of interest is that P_t equals P_s . A little algebra shows that $P_t = P_s$ is equivalent to $P_{10} = P_{01}$, since P_{11} is common to both. Thus, the null hypothesis of McNemar's test is $P_{10} = P_{01}$ and the alternative is that they are unequal. The alternative hypothesis may be one-sided (such as $P_{10} > P_{01}$) or two-sided ($P_{10} \neq P_{01}$).

The null hypothesis may also be stated in terms of the McNemar odds ratio as $OR = 1$. The McNemar odds ratio is not the sample as the regular odds ratio of P_t and P_s . The formula is:

$$OR = \frac{P_{10}}{P_{01}}$$

Notice that the values of P_{11} and P_{00} are not used directly in these hypotheses. It turns out that their individual values are not needed, but their sum is.

For this example, the odds ratio is computed as $0.21/0.04 = 5.25$.

Technical Details

Consider the matched-pairs table again:

		<u>Controls</u>		
<u>Cases</u>		<u>Yes</u>	<u>No</u>	<u>Total</u>
<u>Yes</u>		P11	P10	Pt
<u>No</u>		P01	P00	1-Pt
<u>Total</u>		Ps	1-Ps	1

Pairs with the same response from cases and controls (Yes-Yes and No-No) are called *concordant* pairs. Pairs with different responses (Yes-No and No-Yes) are called *discordant* pairs. McNemar's test statistic is the estimated odds ratio:

$$Mc = \frac{P_{10}}{P_{01}}$$

The sample size problem thus reduces to a study of how many Yes-No's and No-Yes's are needed. Once this has been determined, the overall sample size is found by estimating the proportion of discordant pairs and inflating the sample size appropriately.

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Some power analysis programs follow an approximate procedure. Since the McNemar statistic follows the binomial probability distribution for a fixed number of discordant pairs, they use formulas that use the normal approximation to the binomial and then adjust the sample size depending on the proportion of discordant pairs, $PD = P10 + P01$. This is called the conditional procedure.

One such approximate formula is given by Machin, Campbell, Fayers, and Pinol (1997).

$$N_{pairs} = \frac{\left\{ z_{1-\alpha/s}(OR+1) + z_{1-\beta} \sqrt{(OR+1)^2 - (OR-1)^2 PD} \right\}^2}{(OR-1)^2 PD}$$

where s is the number of sides to the test (one or two), $OR = \frac{P10}{P01}$, $PD = P10 + P01$, and alpha and beta are the usual error rate probabilities.

However, Schork and Williams (1980) published a formula which provides the exact results for the unconditional case using multinomial enumeration of all possible outcomes. This formulation is also available in **PASS**.

$$Power = \sum_{R=r}^N \sum_{n_{12}=0}^{IR} \frac{N!}{(N-R)!n_{12}!(R-n_{12})!} (1-PD)^{N-R} \left(\frac{D+PD}{2} \right)^{n_{12}} \left(\frac{PD-D}{2} \right)^{R-n_{12}}$$

where

$$PD = P10 + P01$$

$$D = P10 - P01$$

N is total of all four cells ($N11 + N12 + N21 + N22$)

r is the smallest integer for which $\left(\frac{1}{2}\right)^r \leq \alpha$

IR is the largest integer such that $\sum_{j=0}^{IR} \binom{R}{j} \left(\frac{1}{2}\right)^R \leq \alpha$

Difference or Odds Ratio

The formula given above is parameterized in terms of the difference. This formula is also used when odds ratios are specified. The program simply converts the OR value into its corresponding D value.

Discussion

The multinomial enumeration (exact) algorithm works for $N < 2000$. Above 2000, computing time goes up and the algorithm has numerical problems. **PASS** lets you select either the multinomial enumeration (exact), or the approximate, solutions. We have found that the approximate solution tends to use a sample size that is about 10% less than the exact solution.

Because of the lengthy computer time necessary to compute the exact answer when $N > 1500$, we suggest that you use the approximate formula to begin with and then revert to the exact formula when you are ready for your final results.

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 beta. This chapter covers two procedures, which have different options. This section documents options that are common to both procedures. Later, unique options for each procedure will be documented.

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*, *Sample Size*, and *Effect Size*. Under most situations, you will select either *Power* or *Sample Size*.

The program is set up to evaluate power directly. For the other parameters such as sample size, a search is made using an iterative procedure until an appropriate value is found.

Note that the value selected here always appears as the vertical axis on the charts.

Power Calculation

Power Calculation Method

Select the method to be used to calculate power. Note that both methods use the McNemar test statistic.

We recommend the Normal Approximation method.

The choices are

- **Multinomial Enumeration**

Power is computed using multinomial enumeration of all possible outcomes when $N \leq \text{Max } N$ (otherwise, the normal approximation is used) as proposed by Schork and Williams (1980).

- **Normal Approximation**

Power is computed conditional on the proportion of discordant events. It uses a normal approximation to the multinomial distribution. This method is presented in Machin, Campbell, Fayers, and Pinol (1997).

The multinomial enumeration formulas require lengthy calculations for large values of N and may be very time consuming. We do not recommend them when $N > 2000$.

Max N for Multinomial Enumeration

For N 's below this value, power calculation formulas using multinomial enumeration are used. When $N > \text{Max } N$, the formula based on the normal approximation to the multinomial is used.

The multinomial enumeration formulas require lengthy calculations for large values of N and may be very time consuming. They should not be used for $N > 2000$.

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Test

Alternative Hypothesis

Specify whether the test is one-sided or two-sided. A one-sided hypothesis uses an inequality as in $P10 > P01$ or Odds Ratio > 1 . A two-sided hypothesis states that the two proportions are not equal without specifying which is greater. If you do not have any special reason to do otherwise, you should use the two-sided option.

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 also commonly used.

If your only interest is in determining the appropriate sample size for a confidence interval, set power to 0.5.

Alpha

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

Sample Size

N (Number of Pairs)

Enter a value (or range of values) for the sample size, N , the number of pairs in the study.

You may enter a range of values such as *100, 200, 300* or *200 to 400 by 50*.

Effect Size

Probability Input Type

This option specifies which of two possible sets of parameters are used.

The choices are

- **Off-Diagonal (P01 and P10)**

This option specifies that the input parameters will be the difference or ratio of P10 and P01 along with the sum of these two parameters ($P10 + P01$ which is called the proportion discordant). This option is difficult because the proportion discordant is often unknown and hard to approximate. This option requires the specification of only two variables: P10 and P01.

- **Marginal (Pt, Ps, and ρ)**

This option specifies that the input parameters will be Pt, Ps, and ρ (the within-subject correlation). This option is easier to use because Pt and Ps are approximately known and ρ can be reasonably guessed. This option requires the specification of three variables: Pt, Ps, and ρ from which the values of P10 and P01 are calculated.

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Effect Size – Off-Diagonal Probabilities (P01 and P10)

P01 and P10 Input Type

Indicate what type of values to enter to specify the effect size. Regardless of the entry type chosen, the calculations are the same. This option is simply given for convenience in specifying the effect size.

Difference (P10-P01)

Only shown when P10 and P10 Input Type = “Differences”

The difference, $P10 - P01$, is a popular parameter to specify because it comes directly from the alternative hypothesis that P_t is not equal P_s . If P_t and P_s are not equal, the obvious question is, by how much? The answer is, by $P10 - P01$ since $P_t - P_s = (P11 + P10) - (P11 + P01) = P10 - P01$. Hence, this is a value that may easily be set.

The range of values is between $-PD$ and PD , except for zero. You may enter a list of value list 0.1, 0.15, 0.2 or 0.05 to 0.20 by 0.05.

McNemar Odds Ratio (P10/P01)

Only shown when P10 and P10 Input Type = “McNemar Odds Ratios”

The odds ratio is a popular parameter to specify because of its simple interpretability and close relationship to the relative risk. An odds ratio of 2.0 means that the odds of the numerator variable is twice the odds of the denominator variable. Note that several values of $P10$ and $P01$ can yield the same odds ratio. For example, $0.2/0.1$ and $0.4/0.2$ both have an odds ratio of 2.0, but are based on very different values of $P10$ and $P01$. Under the null hypothesis, the odds ratio is one. Only positive values are allowed.

You may enter a list of values like 1.5,2.0,3.0 or 1.2 to 2.4 by 0.2.

Proportion Discordant (P10+P01)

In a paired study, this is the proportion of pairs for which the responses differed. It is referred to as the proportion of discordant pairs (PD). It is equal to $P10 + P01$.

Range

$$0 < PD < 1$$

$$PD > |P10 - P01|$$

Ballpark Estimate

If you do not have any other information, you can use the following ballpark estimate which is based on the assumption of independence between the two tests. This will give a value that is probably too high, but at least it will give you a maximum.

$$PD = P_t(1 - P_s) + P_s(1 - P_t)$$

And even better ballpark estimate can be obtained by setting the *Probability Input Type* to *Marginal*, entering reasonable values for P_t , P_s , and ρ , running the procedure, and reading the resulting value of PD on the report. This estimate is better than the above because ρ can be non-zero.

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Effect Size – Marginal Probabilities (Pt, Ps, and ρ)**Pt Input Type**

Indicate what type of values to enter to specify Pt, the treatment event probability. Regardless of the entry type chosen, the same test statistic is used in the power and sample size calculations. This option is simply given for convenience in specifying the Pt.

The choices are

- **Pt**
Enter values for Pt directly.
- **Difference (Pt - Ps)**
Enter values for the difference (Pt - Ps) and values for Ps. The corresponding value of Pt will be computed from these two values.
- **Ratio (Pt / Ps)**
Enter values for the ratio (Pt / Ps) and values for Ps. The corresponding value of Pt will be computed from these two values.
- **Odds Ratio (Or / Oc)**
Enter values for the odds ratio (Or / Oc) and values for Ps. The corresponding value of Pt will be computed from these two values.

Note that $O_r = P_t / (1 - P_t)$ and $O_c = P_s / (1 - P_s)$

Pt (Prob (Yit = 1))

Enter a value for the probability that $Y_{it} = 1$ under the alternative hypothesis, H_1 . Y_{it} is the binary response of observation t for $i = 1, \dots, N$. In a Pre-Post design, observation t would represent the Posttest.

Values must be between 0 and 1.

You can enter a single value such as *0.1* or a series of values such as *0.1 0.2 0.3* or *0.1 to 0.5 by 0.1*.

Note

This value must be different from Ps.

Difference (Pt - Ps)

Enter the difference between Pt and Ps. This difference is used with Ps to calculate the value of Pt using the formula: $P_t = \text{Diff} + P_s$.

You can enter a single value such as *0.05* or a series of values such as *0.03 0.05 0.10* or *0.01 to 0.09 by 0.02*.

Range

Differences must be between -1 and 1. They cannot take on the values -1, 0, or 1. The resulting value of Pt must be between 0 and 1. If it is not, the scenario is skipped.

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Ratio (Pt / Ps)

Enter the ratio of the two probabilities Pt and Ps. This ratio is used with Ps to calculate the value of Pt using the formula: $P_t = \text{Ratio} \times P_s$.

You can enter a single value such as *0.5* or a series of values such as *0.5 0.6 0.7 0.8* or *0.25 to 2.0 by 0.25*.

Range

Ratios must be greater than zero. They cannot take on the value of one. The resulting value of Pt must be between 0 and 1. If it is not, it is changed so that it is between 0 and 1.

Odds Ratio (Ot / Os)

This option specifies the odds ratio between the two probabilities Pt and Ps. This value is used with Ps to calculate the value of Pt.

You can enter a single value such as *0.5* or a series of values such as *0.5 0.6 0.7 0.8* or *1.25 to 2.0 by 0.25*.

Range

Odds ratios must be greater than zero. They cannot take on the value of one.

Ps (Prob (Yis = 1))

Enter a value for the probability that $Y_{is} = 1$ under the both hypotheses, H0 and H1. Y_{is} is the binary response of observation s , $i = 1, \dots, N$. In a Pre-Post design, observation s would represent the Pretest.

Values must be between 0 and 1.

You can enter a single value such as *0.1* or a series of values such as *0.1 0.2 0.3* or *0.1 to 0.5 by 0.1*.

Note

Ps must be different from Pt. That is, you cannot have an effect size of zero.

ρ Input Type

Indicate how to specify ρ , the within-subject correlation. You can specify a value directly, or specify a value for P11 and let the program calculate ρ .

Regardless of the entry type chosen, the same test statistic is used in the power and sample size calculations.

The choices are

- **ρ (Within-Subject Correlation)**

Enter values for ρ , the within-subject correlation.

- **P11 (Prob (Yit = Yis = 1))**

Enter values for P11. This option will usually be used when power is being calculated after an experiment has been run or a reliable estimate of P11 is available from a previous, or pilot, study.

Note: you cannot solve for Effect Size when you select this option.

Tests for Two Correlated Proportions (McNemar Test) **ρ (Within-Subject Correlation)**

Enter one or more values for ρ , the correlation of observations within the same subject (pair).

At least one value must be entered. If multiple values are entered, a separate analysis is performed for each value.

Range

$-\rho_L < \rho < \rho_U$. A value near 0 indicates low correlation. A value near 1 indicates high correlation. The boundaries ρ_L and ρ_U are based on the marginal probabilities, P_t and P_s . They guarantee that P_{11} will be within a suitable range.

Examples are a single value such as *0.5* or a list of values such as *0.5 0.6 0.7* or *0 to 0.9 by 0.1*.

Computing ρ

The formula is

$$\rho = [P_{11} - (P_t)(P_s)] / \text{Square Root} [(P_t)(P_s)(1-P_t)(1-P_s)]$$

P11 (Prob (Yit = Yis = 1))

Enter one or more values for P_{11} , the joint probability that $Y_{is} = 1$ and $Y_{it} = 1$. This option will usually be used when power is being calculated after an experiment has been run or a reliable estimate of P_{11} is available from a previous, or pilot, study.

At least one value must be entered. If multiple values are entered, a separate analysis is performed for each value.

Range

$0 < P_{11} < 1$.

Examples are a single value such as *0.2* or a list of values such as *0.1 0.2 0.3* or *0.1 to 0.9 by 0.1*

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Example 1 – Calculating Power using Off-Diagonal Probabilities

This example will show how to calculate the power of a study for several sample size values. Suppose that a matched case-control study is run in which the odds ratio to detect is 2, PD is 0.3, $N = 50$ to 200 by 50, alpha is 0.05, and power is to be calculated for a two-sided test. The input will only specify the off-diagonal probabilities P_{01} and P_{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 procedure window. You may 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.....	Multinomial Enumeration
Max N for Multinomial Enumeration	3000
Alternative Hypothesis	Two-Sided
Alpha.....	0.05
N (Number of Pairs).....	50 100 150 200
Probability Input Type	Off-Diagonal (P₀₁ and P₁₀)
P ₀₁ and P ₁₀ Input Type.....	McNemar Odds Ratio (P₁₀/P₀₁)
McNemar Odds Ratio (P ₁₀ /P ₀₁).....	2
Proportion Discordant (P ₁₀ +P ₀₁)	0.3

Annotated Output

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

Numeric Results**Numeric Results**

Power Calculation Method: Multinomial Enumeration (Unconditional)
Alternative Hypothesis: Two-Sided

Power	Total Sample Size N	P₁₀	P₀₁	Diff P₁₀-P₀₁	McNemar Odds Ratio P₁₀/P₀₁	Prop Discord P₁₀+P₀₁	Alpha
0.1785	50	0.2000	0.1000	0.1000	2.0000	0.3000	0.050
0.3730	100	0.2000	0.1000	0.1000	2.0000	0.3000	0.050
0.5646	150	0.2000	0.1000	0.1000	2.0000	0.3000	0.050
0.7034	200	0.2000	0.1000	0.1000	2.0000	0.3000	0.050

References

Schork, M. and Williams, G. 1980. 'Number of Observations Required for the Comparison of Two Correlated Proportions.' Communications in Statistics-Simula. Computa., B9(4), 349-357.
Machin, D., Campbell, M., Fayers, P., and Pinol, A. 1997. Sample Size Tables for Clinical Studies, 2nd Edition. Blackwell Science. Malden, MA.

Tests for Two Correlated Proportions (McNemar Test)

Report Definitions

Power is the probability of rejecting a false null hypothesis.

Total Sample Size N is the total number of subjects in the study.

P_{10} is the probability that the treatment response is 'Yes' and the standard response is 'No.'

P_{01} is the probability that the treatment response is 'No' and the standard response is 'Yes.'

Difference $P_{10}-P_{01}$ is the difference between P_{10} and P_{01} . It is equal to the difference between P_t and P_s .

Odds Ratio P_{10}/P_{01} is the McNemar odds ratio which is calculated as P_{10} / P_{01} . It is not equal to the regular odds ratio between P_t and P_s .

Proportion Discordant $P_{10}+P_{01}$ is the sum of the two off-diagonal elements: P_{10} and P_{01} .

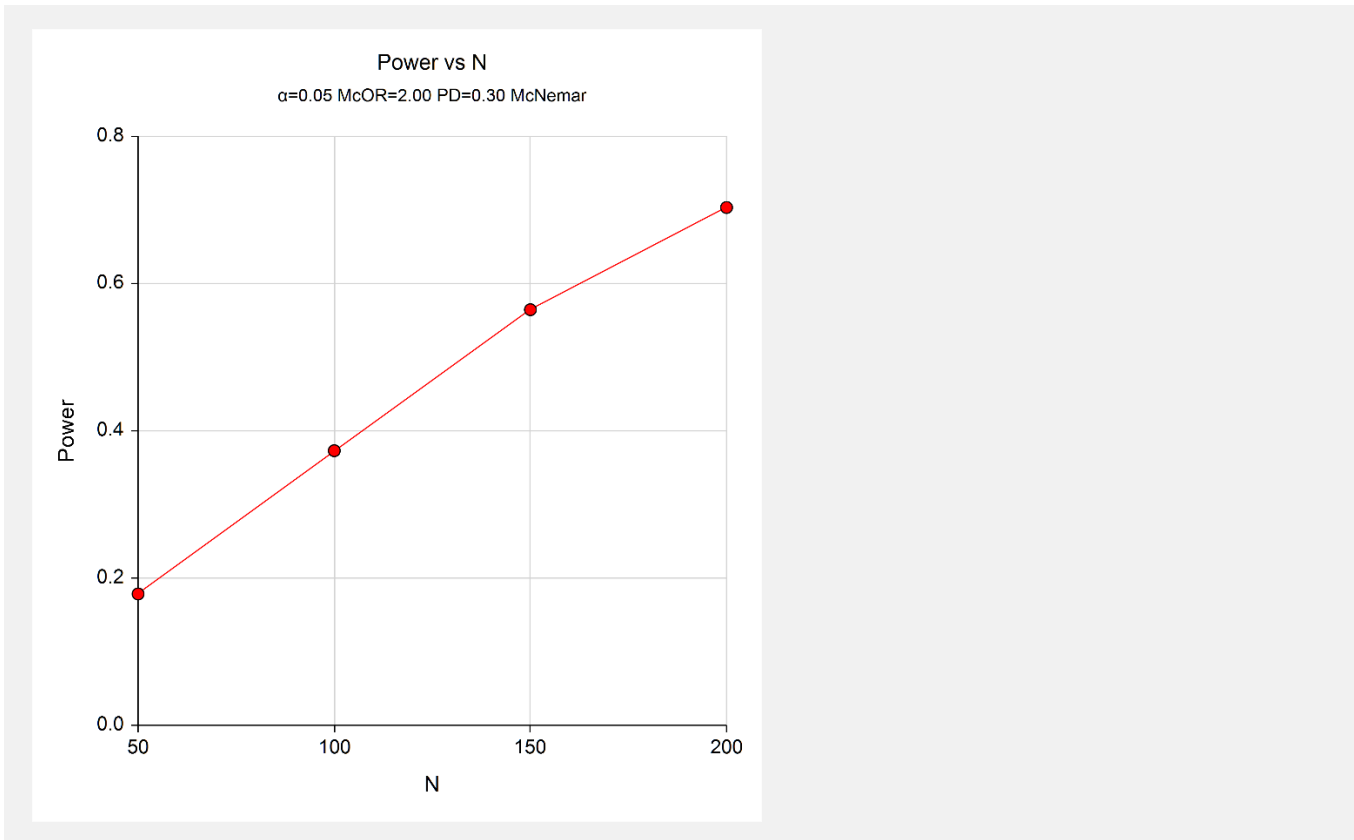
Alpha is the significance level of the test: the probability of rejecting the null hypothesis of equal probabilities when it is true.

Summary Statements

A paired experimental design in which the outcome is binary will use a two-sided McNemar test. A sample of 50 pairs achieves 18% power at a significance level of 0.050 to detect a McNemar odds ratio of 2.0000. The McNemar odds ratio is equivalent to a difference between two paired proportions of 0.1000 which occurs when the proportion in cell 1,0 is 0.2000 and the proportion in cell 0,1 is 0.1000. The proportion of discordant pairs is 0.3000.

This report shows the power for each of the scenarios.

Plot Section



These plots show the power versus the sample size.

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Example 2 – Validation using Schork and Williams (1980)

Schork and Williams (1980) page 354 present a table of sample sizes for various combinations of the other parameters. When the difference is 0.2, the proportion discordant is 0.7, the power is 80%, and the one-sided significance level is 0.025, the sample size is 144.

Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the procedure window. You may 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.....	Multinomial Enumeration
Max N for Multinomial Enumeration	3000
Alternative Hypothesis	One-Sided
Power.....	0.8
Alpha.....	0.025
Probability Input Type.....	Off-Diagonal (P01 and P10)
P01 and P10 Input Type.....	Difference (P10-P01)
Difference (P10-P01)	0.2
Proportion Discordant (P10+P01)	0.7

Output

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

Numeric Results							
Power Calculation Method:		Multinomial Enumeration (Unconditional)					
Alternative Hypothesis:		Two-Sided					
	Total Sample Size			Diff	McNemar Odds Ratio	Prop Discord	
Power	N	P10	P01	P10-P01	P10/P01	P10+P01	Alpha
0.8009	144	0.4500	0.2500	0.2000	1.8000	0.7000	0.025

PASS also finds the sample size to be 144.

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Example 3 – Calculating Sample Size using Marginal Probabilities

This example will show how to calculate the sample when the input is in terms of the marginal probabilities, P_t and P_s and the within-subject correlation. Suppose that a paired study is being planned in which the standard response probability is 0.5; the treatment response probability is assumed to be between 0.55 and 0.65; the within-subject correlation is assumed to be somewhere between 0 and 0.6; alpha is 0.05; power is 0.8 for a two-sided test.

Notice that with this set of input parameters, the difficult to estimate proportion of discordant is not required.

Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the procedure window. You may 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	Sample Size
Power Calculation Method.....	Multinomial Enumeration
Max N for Multinomial Enumeration	3000
Alternative Hypothesis	Two-Sided
Power.....	0.8
Alpha.....	0.05
Probability Input Type	Marginal (P_t, P_s, and ρ)
P_t Input Type	P_t
P_t (Prob ($Y_{it} = 1$)).....	0.55 0.6 0.65
P_s (Prob ($Y_{is} = 1$)).....	0.5
ρ Input Type.....	ρ (Within-Subject Correlation)
ρ (Within-Subject Correlation)	0 0.2 0.4 0.6

Annotated Output

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

Numeric Results								
Power Calculation Method:		Multinomial Enumeration (Unconditional)						
Alternative Hypothesis:		Two-Sided						
Power	Total Sample Size N	P_t	P_s	P_t - P_s Diff	Within Subj Corr ρ	Prop Discord $P_{10}+P_{01}$	Joint Prob Both Obs=1 P_{11}	Alpha
0.8000	1606	0.5500	0.5000	0.0500	0.0000	0.5000	0.2750	0.050
0.8002	1293	0.5500	0.5000	0.0500	0.2000	0.4005	0.3247	0.050
0.8002	978	0.5500	0.5000	0.0500	0.4000	0.3010	0.3745	0.050
0.8002	662	0.5500	0.5000	0.0500	0.6000	0.2015	0.4242	0.050
0.8002	408	0.6000	0.5000	0.1000	0.0000	0.5000	0.3000	0.050
0.8006	330	0.6000	0.5000	0.1000	0.2000	0.4020	0.3490	0.050
0.8005	252	0.6000	0.5000	0.1000	0.4000	0.3040	0.3980	0.050
0.8016	173	0.6000	0.5000	0.1000	0.6000	0.2061	0.4470	0.050
0.8000	183	0.6500	0.5000	0.1500	0.0000	0.5000	0.3250	0.050
0.8025	149	0.6500	0.5000	0.1500	0.2000	0.4046	0.3727	0.050
0.8013	115	0.6500	0.5000	0.1500	0.4000	0.3092	0.4204	0.050
0.8030	77	0.6500	0.5000	0.1500	0.6000	0.2138	0.4681	0.050

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Report Definitions

Power is the probability of rejecting a false null hypothesis.

Total Sample Size N is the total number of subjects in the study.

Pt is the probability of a "true" response in the treatment observation.

Ps is the probability of a "true" response in the standard observation.

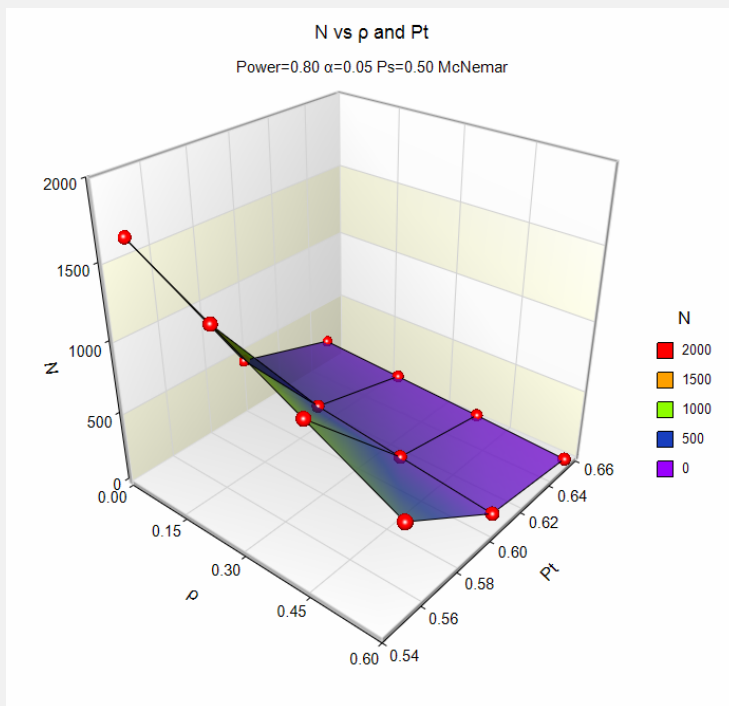
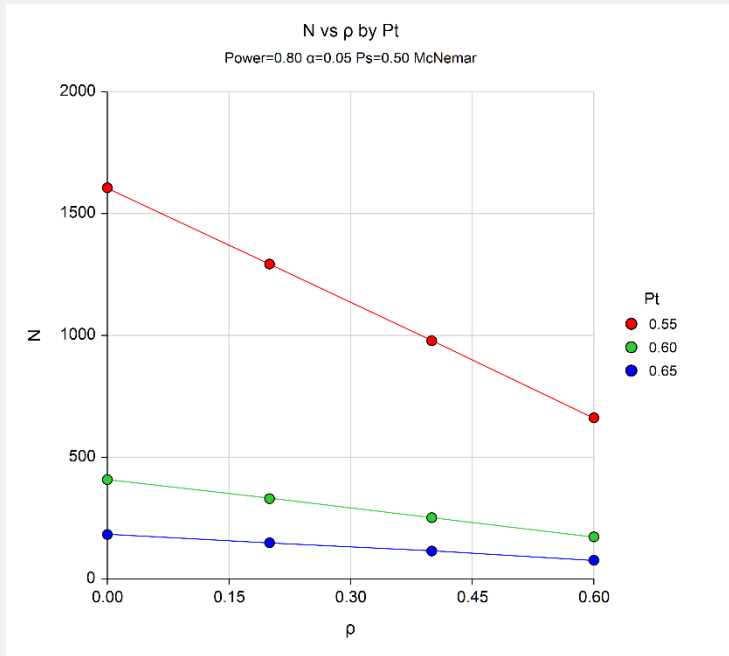
Diff (Pt-Ps) is the difference between the two probabilities.

ρ (Within Subj Corr) is the correlation between the two observations within a subject.

P11 (Joint Prob Both Obs=1) is the joint probability that both observations in a pair are true (equal to '1').

Alpha is the significance level of the test: the probability of rejecting the null hypothesis of equal probabilities when it is true.

Chart Section



Tests for Two Correlated Proportions (McNemar Test)

Example 4 – Computing Sample Size for a 2x2 Cross-Over Design

Julious (2010) indicates on page 167 that a 2x2 cross-over trial can be analyzed using the McNemar test if the period effect is ignored. This example will show you how to estimate the sample size for a 2x2 cross-over trial based on McNemar test.

In example 10.1 on page 170, Julious (2010) provides a table with both joint and marginal probabilities. From this table, we find that $P_t = 0.72$, $P_s = 0.56$, and $P_{11} = 0.4$. We will calculate the required sample size using the conditional (normal approximation) power formulas. The required power is 90% and the two-sided significance level is 0.05. He estimates the required sample size as 190.

Note that Julious (2010) uses a slightly different asymptotic sample size formula (see page 169) from that used by this procedure.

Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the procedure. You may make the appropriate entries as listed below or open **Example 4a** 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
Alternative Hypothesis	Two-Sided
Power.....	0.9
Alpha.....	0.05
Probability Input Type	Marginal (Pt, Ps, and p)
Pt Input Type	Pt
Pt (Prob (Yit = 1)).....	0.72
Ps (Prob (Yis = 1)).....	0.56
p Input Type.....	P11 (Prob (Yit = Yis = 1))
P11 (Prob (Yit = Yis = 1))	0.4

Output

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

Numeric Results								
Power Calculation Method:		Normal Approximation (Conditional)						
Alternative Hypothesis:		Two-Sided						
Power	Total Sample Size N	Pt	Ps	Pt-Ps Diff	Within Subj Corr p	Prop Discord P10+P01	Joint Prob Both Obs=1 P11	Alpha
0.9003	193	0.7200	0.5600	0.1600	-0.0144	0.4800	0.4000	0.050

PASS finds the sample size to be 193. It's not surprising that the sample size is slightly different from Julious (2010) because the calculation formulas are not the same.

Tests for Two Correlated Proportions (McNemar Test)

If we set the Power Calculation Method to *Multinomial Enumeration* and rerun this example, we obtain the following results (Example 4b).

Numeric Results

Numeric Results								
Power Calculation Method:		Multinomial Enumeration (Unconditional)						
Alternative Hypothesis:		Two-Sided						
Power	Total Sample Size N	Pt	Ps	Pt-Ps Diff	Within Subj Corr ρ	Prop Discord P10+P01	Joint Prob Both Obs=1 P11	Alpha
0.9008	203	0.7200	0.5600	0.1600	-0.0144	0.4800	0.4000	0.050

PASS finds the sample size to be 203 in the unconditional case. This is about a 5% increase in sample size over the 193 in the conditional case.