Chapter 252

Tests for Two Ordered Categorical Variables

Introduction

This module computes power and sample size for tests of ordered categorical data such as Likert scale data. Assuming proportional odds, such data can be analyzed with a z-test, ordinal logistic regression, ordered logistic regression, ordered logit model, proportional odds model, or the Mann-Whitney test. The power and sample size formulae presented here are consistent with any of these analysis methods. The results used here were presented in a paper by Whitehead (1993). They are also mentioned in the book by Julious (2010) and Machin et al (2018).

Ordered categorical data often results from surveys such as a quality of life (QoL) survey in which responses are categories such as *very good*, *good*, *moderate*, *poor*. When there are only two categories, an analysis using two proportions should be used. When there are more than two responses, and those responses can be ordered, the techniques described in this chapter can be used.

Technical Details

Suppose a variable has K possible responses $C_1, \ldots, C_K$. Further suppose that these categories can be ordered so that C_k is more desirable than C_j if $k < j$. Hence C_1 is the best outcome and C_K is the worst. This procedure compares the results from two groups which will be called control (1) and experimental (2). The number of respondents falling within the k^{th}category of the control group is labeled N_{1k}. The total number of subjects in the control group is $N_1$and in the experimental group is N_2. The total sample size of the study is $N = N_1 + N_2$.

Let p_{2k} denote the probability that an individual in the experimental group gives response C_k, and let Q_{2k} be the probability of an outcome of C_k or better. Thus $Q_{2k} = \sum_{j=1}^{k} p_{2j}$.

Define p_1 and Q_{1k} similarly for the control group.

Define the odds ratio for a particular category as

$$OR_k = \frac{\frac{Q_{2k}}{1-Q_{2k}}}{\frac{Q_{1k}}{1-Q_{1k}}} \quad k = 1, \ldots, K-1.$$

This measures the advantage of the experimental group over the control group. An OR_k greater than one indicates that the experimental treatment (group 2) is better than the control treatment (group 1).

Proportional Odds

The proportional odds model assumes that all of the odds ratios OR_k are equal to a common value OR. That is, the *proportional odds* assumption is that $OR_1 = \cdots = OR_{K-1} = OR$. Thus, the whole pattern of response differences can be summarized by a single parameter.

The formulae to follow use the fact that efficient score *Y* is asymptotically normally distributed when $Log(OR)$ is small and *N* is large. The test statistic and power formulae are as follows.

$$Y = \frac{1}{N+1}\sum_{k=1}^{K} N_{1k}(L_{1k} - U_{1k})$$

$$Z = \frac{Y - \mu_Y}{\sigma_Y}$$

$$L_{1k} = N_{11} + \cdots + N_{1(k-1)}, \quad k = 2, \ldots, K$$

$$L_{2k} = N_{21} + \cdots + N_{2(k-1)}, \quad k = 2, \ldots, K$$

$$U_{1k} = N_{1(k+1)} + \cdots + N_{1K}, \quad k = 1, \ldots, K-1$$

$$U_{2k} = N_{2(k+1)} + \cdots + N_{2K}, \quad k = 1, \ldots, K-1$$

$$L_{11} = U_{1K} = 0$$

$$L_{21} = U_{2K} = 0$$

$$\mu_Y = \text{Log}(OR)V$$

$$\sigma_Y^2 = V$$

$$V = \frac{N_1 N_2 N}{3(N+1)^2}\left\{1 - \sum_{k=1}^{K}\left[\frac{N_{1k} + N_{2k}}{N}\right]^3\right\} \approx \frac{N_1 N_2 N}{3(N+1)^2}\left\{1 - \sum_{k=1}^{K}\left[\frac{p_{1k} + p_{2k}}{2}\right]^3\right\}$$

The null hypothesis $H_0\text{: } OR = 1$ can be tested against the alternative $H_1\text{: } OR \neq 1$ by computing Z and rejecting if *Z* is greater than $z_{\alpha/2}$. That is,

$$\text{P}(Z > z_\alpha | OR = 1) = \alpha/2$$

The power is the probability of rejecting a false null hypothesis, thus the power for a specified value $OR_R$is

$$Power = \text{P}\left(Z > z_{\frac{\alpha}{2}} | OR = OR_R\right) = 1 - \Phi\left(z_{\frac{\alpha}{2}} - OR_R\sqrt{V}\right)$$

If a one-sided test is needed, replace $\alpha/2$with α.

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.

Please note that in this procedure, we have denoted group 1 as the control group and group 2 as the experimental group so that we are consistent with Whitehead (1993).

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. The parameters that may be selected are *OR or Log(OR)*, *Sample Size*, or *Power*.

Test

Null Hypothesis

Indicate whether the hypothesis is one-sided or two-sided. If *two-sided* is selected, alpha is automatically divided by 2, so you do not need to manually divide alpha by 2.

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. In this procedure, a type-II error occurs when you fail to reject the null hypothesis of $OR = 1$ when, in fact, $OR \neq 0$.

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. A type-I error occurs when a true null hypothesis is rejected. In this procedure, a type-I error occurs when you reject the null hypothesis that $OR = 1$ when in fact it is.

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*.

Note that when you are analyzing a two-sided test, you should enter alpha, not alpha/2.

Sample Size (When Solving for Sample Size)

Group Allocation

Select the option that describes the constraints on *N1* or *N2* or both.

The options are

- **Equal (N1 = N2)**
  This selection is used when you wish to have equal sample sizes in each group. Since you are solving for both sample sizes at once, no additional sample size parameters need to be entered.

- **Enter N1, solve for N2**
  Select this option when you wish to fix *N1* at some value (or values), and then solve only for *N2*. Please note that for some values of *N1*, there may not be a value of *N2* that is large enough to obtain the desired power.

- **Enter N2, solve for N1**
  Select this option when you wish to fix *N2* at some value (or values), and then solve only for *N1*. Please note that for some values of *N2*, there may not be a value of *N1* that is large enough to obtain the desired power.

- **Enter R = N2/N1, solve for N1 and N2**
  For this choice, you set a value for the ratio of *N2* to *N1*, and then PASS determines the needed *N1* and *N2*, with this ratio, to obtain the desired power. An equivalent representation of the ratio, *R*, is

$$N2 = R * N1.$$

- **Enter percentage in Group 1, solve for N1 and N2**
  For this choice, you set a value for the percentage of the total sample size that is in Group 1, and then PASS determines the needed *N1* and *N2* with this percentage to obtain the desired power.

N1 (Sample Size, Group 1)

This option is displayed if Group Allocation = "Enter N1, solve for N2"

N1 is the number of items or individuals sampled from the Group 1 population.

N1 must be ≥ 2. You can enter a single value or a series of values.

N2 (Sample Size, Group 2)

This option is displayed if Group Allocation = "Enter N2, solve for N1"

N2 is the number of items or individuals sampled from the Group 2 population.

N2 must be ≥ 2. You can enter a single value or a series of values.

R (Group Sample Size Ratio)

This option is displayed only if Group Allocation = "Enter R = N2/N1, solve for N1 and N2."

R is the ratio of *N2* to *N1*. That is,

$$R = N2 / N1.$$

Use this value to fix the ratio of *N2* to *N1* while solving for *N1* and *N2*. Only sample size combinations with this ratio are considered.

N2 is related to *N1* by the formula:

$$N2 = [R \times N1],$$

where the value *[Y]* is the next integer $\geq Y$.

For example, setting *R* = 2.0 results in a Group 2 sample size that is double the sample size in Group 1 (e.g., *N1* = 10 and *N2* = 20, or *N1* = 50 and *N2* = 100).

R must be greater than 0. If *R* < 1, then *N2* will be less than *N1*; if *R* > 1, then *N2* will be greater than *N1*. You can enter a single or a series of values.

Percent in Group 1

This option is displayed only if Group Allocation = "Enter percentage in Group 1, solve for N1 and N2."

Use this value to fix the percentage of the total sample size allocated to Group 1 while solving for *N1* and *N2*. Only sample size combinations with this Group 1 percentage are considered. Small variations from the specified percentage may occur due to the discrete nature of sample sizes.

The Percent in Group 1 must be greater than 0 and less than 100. You can enter a single or a series of values.

Sample Size (When Not Solving for Sample Size)

Group Allocation

Select the option that describes how individuals in the study will be allocated to Group 1 and to Group 2.

The options are

- **Equal (N1 = N2)**
  This selection is used when you wish to have equal sample sizes in each group. A single per group sample size will be entered.

- **Enter N1 and N2 individually**
  This choice permits you to enter different values for *N1* and *N2*.

- **Enter N1 and R, where N2 = R * N1**
  Choose this option to specify a value (or values) for *N1*, and obtain *N2* as a ratio (multiple) of *N1*.

- **Enter total sample size and percentage in Group 1**
  Choose this option to specify a value (or values) for the total sample size (*N*), obtain *N1* as a percentage of *N*, and then *N2* as *N* - *N1*.

Sample Size Per Group

This option is displayed only if Group Allocation = "Equal (N1 = N2)."

The Sample Size Per Group is the number of items or individuals sampled from each of the Group 1 and Group 2 populations. Since the sample sizes are the same in each group, this value is the value for *N1*, and also the value for *N2*.

The Sample Size Per Group must be ≥ 2. You can enter a single value or a series of values.

N1 (Sample Size, Group 1)

*This option is displayed if Group Allocation = "Enter N1 and N2 individually" or "Enter N1 and R, where N2 = R * N1."*

N1 is the number of items or individuals sampled from the Group 1 population.

N1 must be ≥ 2. You can enter a single value or a series of values.

N2 (Sample Size, Group 2)

This option is displayed only if Group Allocation = "Enter N1 and N2 individually."

N2 is the number of items or individuals sampled from the Group 2 population.

N2 must be ≥ 2. You can enter a single value or a series of values.

R (Group Sample Size Ratio)

*This option is displayed only if Group Allocation = "Enter N1 and R, where N2 = R * N1."*

R is the ratio of *N2* to *N1*. That is,

$$R = N2/N1$$

Use this value to obtain *N2* as a multiple (or proportion) of *N1*.

N2 is calculated from *N1* using the formula:

$$N2=[R \times N1],$$

where the value *[Y]* is the next integer ≥ *Y*.

For example, setting *R* = 2.0 results in a Group 2 sample size that is double the sample size in Group 1.

R must be greater than 0. If *R* < 1, then *N2* will be less than N1; if *R* > 1, then *N2* will be greater than *N1*. You can enter a single value or a series of values.

Total Sample Size (N)

This option is displayed only if Group Allocation = "Enter total sample size and percentage in Group 1."

This is the total sample size, or the sum of the two group sample sizes. This value, along with the percentage of the total sample size in Group 1, implicitly defines *N1* and *N2*.

The total sample size must be greater than one, but practically, must be greater than 3, since each group sample size needs to be at least 2.

You can enter a single value or a series of values.

Percent in Group 1

This option is displayed only if Group Allocation = "Enter total sample size and percentage in Group 1."

This value fixes the percentage of the total sample size allocated to Group 1. Small variations from the specified percentage may occur due to the discrete nature of sample sizes.

The Percent in Group 1 must be greater than 0 and less than 100. You can enter a single value or a series of values.

Effect Size

P1's Input Type

Specify how you want to enter the category proportions for group 1, the control group.

The choices are

- **Enter P11, P12, ..., P1K Pattern**
  Use this option when you only want to enter one set of category proportions. You will be able to enter them in the box below this one.

- **Enter Columns containing sets of P1's**
  Use this option when you want to enter multiple sets of category proportions so that you can easily compare them. You will enter one or more sets of values in the columns of the spreadsheet.

P11, P12, ..., P1K Pattern

Enter a list of positive values that represent the pattern of the response proportions (or probabilities) in each category of group 1. These values are then rescaled so that they sum to one.

Once rescaled, they become the actual response proportions of group 1. These values are then combined with the odds ratio to generate the corresponding response proportions of group 2.

Number of Categories

The number of categories is implied by the number of items in this list.

Example

For example, an entry of "2 3 4 1" implies that there are four categories and that 20% are category 1, 30% are category 2, 40% are category 3, and 10% are category 4. That is, the response proportions are

P11 = 0.2, P12 = 0.3, P13 = 0.4, and P14 = 0.1.

Discussion

The categories are assumed to be ordinal. That is, the first category is assumed to be the best outcome and the last category is the worst. The categories are assumed to be ordered so that each is no better than the previous category. Likert scales are good examples of ordinal categories.

For example, the categories might be

Best, Above Average, Average, Below Average, Worst

Note that the category proportions themselves are not required to have an ordering.

Rescaling to Sum to One

Note that these values are rescaled so they sum to one. This is easily accomplished by dividing each value by the total of all values.

For example, the values "20 30 40 10" (which sum to 100) are adjusted to "0.2 0.3 0.4 0.1" (which sum to one).

Range

You can enter any list of positive (non-zero) numbers. The number of values is the number of categories. For example, if you wanted to indicate that you have five, equally likely categories, you could enter "1 1 1 1 1".

Columns containing sets of P1's

Enter one or more spreadsheet columns containing vertical lists of P1's. These values are used to generate the category proportions in group 1, the control group. Each column is analyzed separately.

Columns

Enter a list of positive values down a column that represent the pattern of the response proportions (or probabilities) in each category of group 1. These values are then rescaled so that they sum to one.

Once rescaled, they become a set of response proportions for the categories of group 1.

These values are then combined with the odds ratio to generate the corresponding response proportions of group 2.

Number of Categories

The number of categories is implied by the number of items in this list.

Example

For example, an entry of "2 3 4 1" down column 1 implies that there are four categories and that 20% are category 1, 30% are category 2, 40% are category 3, and 10% are category 4. That is, the response proportions are

P11 = 0.2, P12 = 0.3, P13 = 0.4, and P14 = 0.1.

Discussion

The categories are assumed to be ordinal. That is, the first category is assumed to be the best outcome and the last category is the worst. The categories are assumed to be arranged so that each is no better than the previous one. Likert scales are good examples of ordinal categories.

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For example, the values "20 30 40 10" (which sum to 100) are adjusted to "0.2 0.3 0.4 0.1" (which sum to one).

Range

You can enter any list of positive (non-zero) numbers. The number of values is the number of categories. For example, if you wanted to indicate that you have five, equally likely categories, you could enter "1 1 1 1 1" in particular column.

Using the spreadsheet

Press the Spreadsheet icon (directly to the right) to select the columns and then enter the values.

Press the Input Spreadsheet icon (to the right and slightly up) to view/edit the spreadsheet. Also note that you can obtain the spreadsheet by selecting "Tools", then "Input Spreadsheet", from the menus.

On the spreadsheet, the P1's are entered going down.

Examples (assuming different K's)

C1	C2	C3
10	1	30
10	2	40
10	2	50
10	4	

Definition of a Single Column

Each column gives one set of unscaled proportions. Each column results in a new scenario which is analyzed separately.

Valid Entries

All numeric values > 0 are valid.

Column Names

The column names (C1, C2, ...) can be changed by right-clicking on them in the spreadsheet.

Odds Ratio Input Type

Specify whether you want to enter the odds ratio directly or enter its logarithm.

Note that the odds ratio is the ratio of the odds for group 2 divided by the odds for group 1.

The options are

- **Enter OR (Odds Ratio)**
  Enter the odds ratio directly.

- **Enter Log(OR) (Log Odds Ratio)**
  Enter the logarithm (Base e) of the odds ratio.

OR (Odds Ratio)

Enter one or more values for OR, the odds ratio. This value represents the effect size to be detected by the study. The ratio is formed by dividing the odds for group 2 by the odds for group 1. The odds ratio is assumed to be constant for all categories.

Impact of the Size of OR

Odds ratios less than one will increase the P2 values early in the list and decrease those that are later in the list. Odds ratios greater than one have the opposite effect. You can see examples of this in the numeric reports.

Range

OR ≠ 1. OR > 0.

Examples

0.25 0.5 0.75

1.2 to 2 by 0.2

Example 1 – Finding the Sample Size

Suppose a clinical trial is planned to compare the response to certain treatment. The subjects are divided into two groups: those that will receive the current treatment and those that will receive an experimental treatment. Three months after the administration of the treatment, the subjects rate their response as *poor, moderate, good, and very good.* Historically, the responses have been about 20% *poor*, 50% *moderate*, 20% *good*, and 10% *very good*.

The researchers want to consider a range of possible value of *OR* from 1.5 to 2.5. They want to look at the sample size requirements to achieve a power of 0.90. They want to set alpha to 0.05 and analyze the results with a two-sided test.

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 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	**Sample Size**
Null Hypothesis	**Two-Sided**
Power	**0.9**
Alpha	**0.05**
Group Allocation	**Equal (N1 = N2)**
P1's Input Type	**Enter P11, P12, ..., P1K Pattern**
P11, P12, ..., P1K Pattern	**2 5 2 1**
Odds Ratio Input Type	**OR (Odds Ratio)**
OR (Odds Ratio)	**1.5 2 2.5**

Annotated Output

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

Numeric Results

Numeric Results
Hypotheses: H0: OR = 1 vs. H1: OR ≠ 1
Group 1: Control Group
Group 2: Experimental Group

Power	N1	N2	N	Num Cat's K	Odds Ratio OR	Grp 1 Prop's Set P1	Grp 2 Prop's Set P2	Alpha
0.9006	443	443	886	4	1.500	P1(1)	P2(1)	0.050
0.9017	151	151	302	4	2.000	P1(1)	P2(2)	0.050
0.9017	86	86	172	4	2.500	P1(1)	P2(3)	0.050

Set(Set Number): Values
P1(1): 0.20, 0.50, 0.20, 0.10
P2(1): 0.14, 0.47, 0.25, 0.14
P2(2): 0.11, 0.43, 0.28, 0.18
P2(3): 0.09, 0.39, 0.30, 0.22

References

Whitehead, John. 1993. 'Sample Size Calculations for Ordered Categorical Data.' Statistics in Medicine, 12, 2257-2271.
Julious, Steven A. 2010. Sample Sizes for Clinical Trials. Chapman & Hall/CRC. Boca Raton, Fl.
Machin, D., Campbell, M., Tan, S.B., and Tan, S.H. 2018. Sample Size Tables for Clinical Studies, 4th Edition. John Wiley & Sons. Hoboken, NJ.

Report Definitions

Power is the probability of rejecting a false null hypothesis.
N1 is the number of subjects in the group 1, the control group.
N2 is the number of subjects in the group 2, the experimental group.
N is the total sample size, N1 + N2.
Num Cat's K is the number of categories in the response variable.
Odds Ratio OR is the odds ratio = odds2/odds1.
Grp 1 Prop's Set P1 is the name of the set containing the response proportions for each of the K categories in group 1, the control group.
Grp 2 Prop's Set P2 is the name of the set containing the response proportions for each of the K categories in group 2, the experimental group.
Alpha is the probability of rejecting a true null hypothesis.

Summary Statements

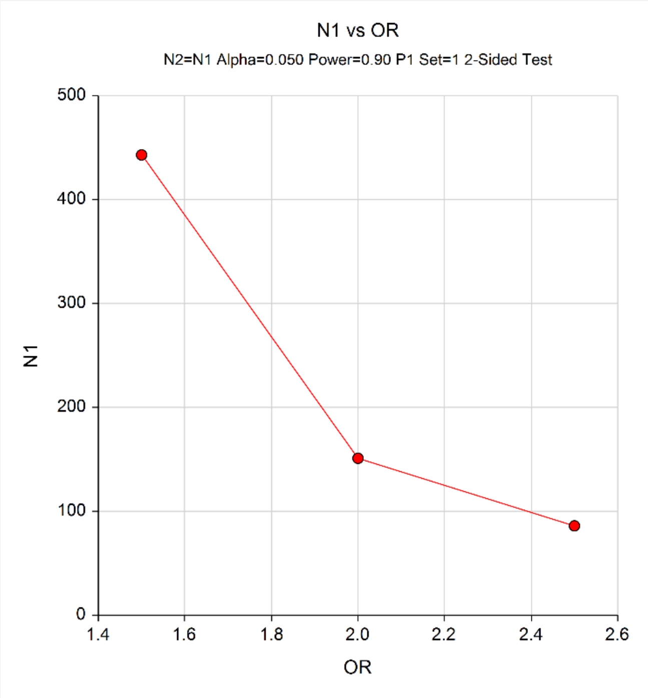
Samples of 443 subjects in the control group and 443 subjects in experimental group achieve 90% power to detect an odds ratio of 1.500 when the significance level (alpha) is 0.050 using a two-sided test. The number of response categories is 4. The response proportions in group 1 are estimated to be 0.20, 0.50, 0.20, 0.10. The response proportions in group 2 are estimated to be 0.14, 0.47, 0.25, 0.14.

This report shows the numeric results of this sample size study. The definitions of the items on the report are given in the Report Definitions section.

We would like to point out a couple of things. Note that the scores of the experiment group increase over those of the control group.

Also note the impact that the increasing odds ratios have had on the response probabilities. The proportion of those responding “Poor” has fallen from 0.20 to 0.09. The corresponding proportion of those responding “Very Good” has risen from 0.1 to 0.22.

Plots Section



This plot gives a visual presentation to the results in the Numeric Report.

Example 2 – Validation using Whitehead (1993)

Whitehead (1993) has an example in which he calculates the sample size to be 94 when *Log(OR)* is -0.887, alpha is 0.05, power is 90%, the control group proportions are 0.2, 0.5, 0.2, and 0.1.

Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load the 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**
Null Hypothesis	**Two-Sided**
Power	**0.9**
Alpha	**0.05**
Group Allocation	**Equal (N1 = N2)**
P1's Input Type	**Enter P11, P12, ..., P1K Pattern**
P11, P12, ..., P1K Pattern	**2 5 2 1**
Odds Ratio Input Type	**Log(OR) (Log Odds Ratio)**
Log(OR) (Log Odds Ratio)	**-0.887**

Output

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

Numeric Results

Numeric Results
Hypotheses: H0: Log(OR) = 0 vs. H1: Log(OR) ≠ 0
Group 1: Control Group
Group 2: Experimental Group

Power	N1	N2	N	Num Cat's K	Log Odds Ratio Log(OR)	Grp 1 Prop's Set P1	Grp 2 Prop's Set P2	Alpha
0.9015	95	95	190	4	-0.887	P1(1)	P2(1)	0.050

Set(Set Number): Values
P1(1): 0.200, 0.500, 0.200, 0.100
P2(1): 0.378, 0.472, 0.106, 0.044

PASS found the required sample size as 95 per group. The increase from 94 to 95 was due to rounding. We found that the power for 94 was 0.8985, just less than the goal of 0.90. We note that the values of P2 match those in Whitehead (1993) exactly.

Example 3 – Calculating Sample Size for a COVID-19 Clinical Trial

This example will show how this procedure might be used in planning a clinical trial to assess the effectiveness of a treatment in combatting COVID-19. The study outcome on which the sample size will be based is the six-category ordinal scale of illness severity used in a recent trial.

The hypothetical trial that is being planned here will use the following six-point ordinal scale.

0) Discharge (alive).
1) Hospital admission, not requiring supplemental oxygen.
2) Hospital admission, requiring supplemental oxygen.
3) Hospital admission, requiring high-flow nasal cannula or non-invasive mechanical ventilation.
4) Hospital admission, requiring extracorporeal membrane oxygenation or invasive mechanical ventilation.
5) Death.

A recent trial provided the following response distribution for the placebo group at day 14: 23%, 13%, 36%, 10%, 9%, and 9%.

Using this response distribution for controls, determine the sample necessary to compare two groups consisting of a control group and a treatment group. Assume that twice as many subjects will be assigned to the treatment group as to the control group. Also assume that alpha is 0.05 and power is 0.90. This analysis will calculate the required sample sizes to detect odds ratios of 0.8, 0.7, and 0.6.

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 then make the appropriate entries as listed below, or open **Example 3** by going to the **File** menu and choosing **Open Example Template**.

Option	Value
Design Tab	
Solve For	**Sample Size**
Null Hypothesis	**Two-Sided**
Power	**0.9**
Alpha	**0.05**
Group Allocation	**Enter R = N2/N1, solve for N1 and N2**
R	**2**
P1’s Input Type	**Enter P11, P12, ..., P1K Pattern**
P11, P12, ..., P1K Pattern	**23 13 36 10 9 9**
Odds Ratio Input Type	**OR (Odds Ratio)**
OR (Odds Ratio)	**0.8 0.7 0.6**

Output

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

Numeric Results

Numeric Results
Hypotheses: H0: OR = 1 vs. H1: OR ≠ 1
Group 1: Control Group
Group 2: Experimental Group

Power	N1	N2	N	Num Cat's K	Target N2/N1 R	Odds Ratio OR	Grp 1 Prop's Set P1	Grp 2 Prop's Set P2	Alpha
0.9002	195	390	585	6	2.00	0.600	P1(1)	P2(1)	0.050
0.9003	399	798	1197	6	2.00	0.700	P1(1)	P2(2)	0.050
0.9002	1017	2034	3051	6	2.00	0.800	P1(1)	P2(3)	0.050

Set(Set Number): Values
P1(1): 0.230, 0.130, 0.360, 0.100, 0.090, 0.090
P2(1): 0.332, 0.152, 0.327, 0.073, 0.060, 0.056
P2(2): 0.299, 0.146, 0.340, 0.081, 0.068, 0.065
P2(3): 0.272, 0.141, 0.350, 0.088, 0.076, 0.073

PASS found the required sample sized for the three odds ratios. Note that N2 = 2(N1) in all cases as request. Also note that the predicted distributions of responses anticipate a decrease in the value of P21 as the odds ratio decreases from 0.8 to 0.6.

Example 4 – COVID-19 Continued – Comparing Various Response Distributions

Continuing with Example 3, the researchers would like to analyze the impact of the control response probability distribution on the required sample size. To do this, the example will compare the results for the following distributional patterns:

All Equal: 1, 1, 1, 1, 1, 1

Pilot Data: 23, 13, 36, 10, 9, 9

Linear Decreasing: 6, 5, 4, 3, 2, 1

First Large: 15, 1, 1, 1, 1, 1

These patterns will be loaded in the spreadsheet. The spreadsheet will appear as follows:

Eq	PD	LD	FL
1	23	6	3
1	13	5	3
1	36	4	2
1	10	3	2
1	9	2	1
1	9	1	1

The rest of the parameters will remain the same.

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 then make the appropriate entries as listed below, or open **Example 4** by going to the **File** menu and choosing **Open Example Template**.

Option	Value
Design Tab	
Solve For	**Sample Size**
Null Hypothesis	**Two-Sided**
Power	**0.9**
Alpha	**0.05**
Group Allocation	**Enter R = N2/N1, solve for N1 and N2**
R	**2**
P1’s Input Type	**Enter columns containing sets of P1’s**
Columns containing sets of P1’s	**1-4**
Odds Ratio Input Type	**OR (Odds Ratio)**
OR (Odds Ratio)	**0.8 0.7 0.6**

Output

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

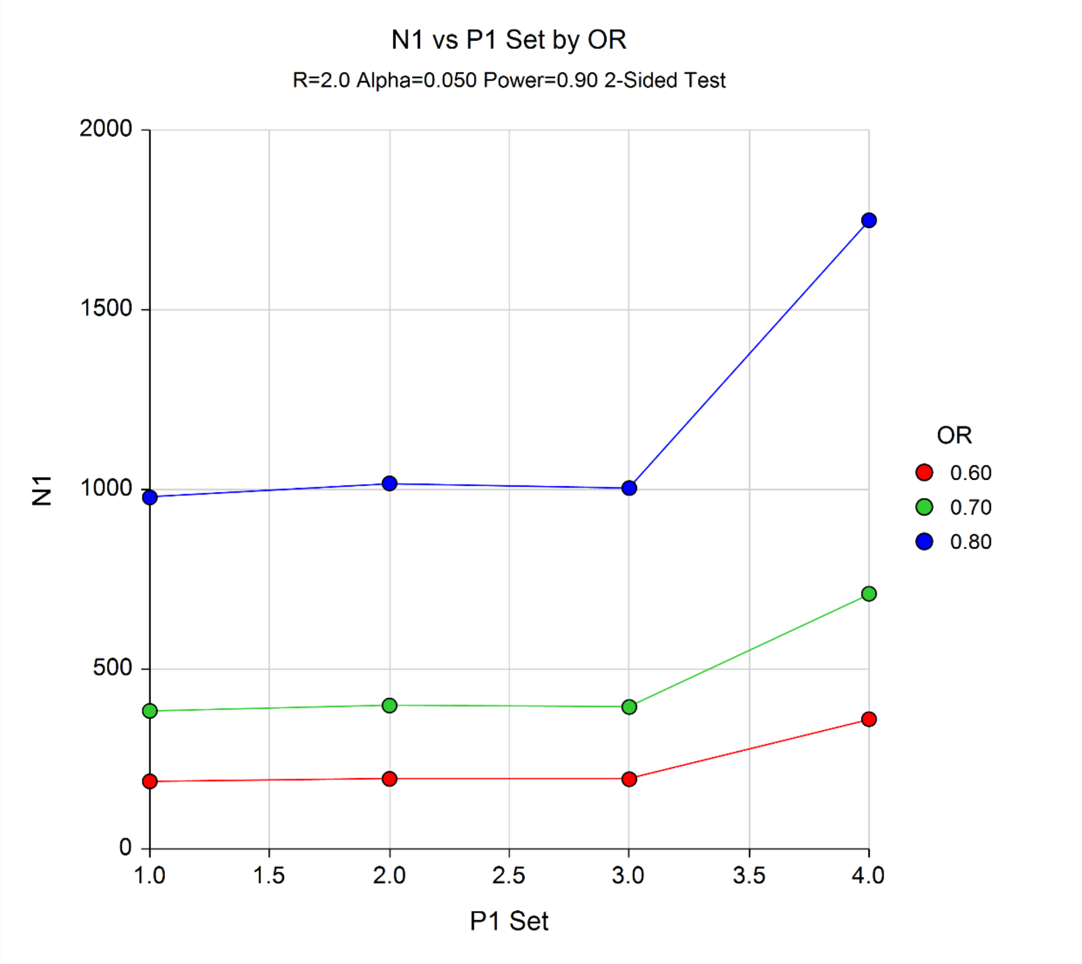
Numeric Results

Numeric Results
Hypotheses: H0: OR = 1 vs. H1: OR ≠ 1
Group 1: Control Group
Group 2: Experimental Group

Power	N1	N2	N	Num Cat's K	Target N2/N1 R	Odds Ratio OR	Grp 1 Prop's Set P1	Grp 2 Prop's Set P2	Alpha
0.9009	188	376	564	6	2.00	0.600	Eq(1)	P2(1)	0.050
0.9005	384	768	1152	6	2.00	0.700	Eq(1)	P2(2)	0.050
0.9001	978	1956	2934	6	2.00	0.800	Eq(1)	P2(3)	0.050
0.9002	195	390	585	6	2.00	0.600	PD(2)	P2(4)	0.050
0.9003	399	798	1197	6	2.00	0.700	PD(2)	P2(5)	0.050
0.9002	1017	2034	3051	6	2.00	0.800	PD(2)	P2(6)	0.050
0.9001	194	388	582	6	2.00	0.600	LD(3)	P2(7)	0.050
0.9001	395	790	1185	6	2.00	0.700	LD(3)	P2(8)	0.050
0.9001	1004	2008	3012	6	2.00	0.800	LD(3)	P2(9)	0.050
0.9003	361	722	1083	6	2.00	0.600	FL(4)	P2(10)	0.050
0.9002	710	1420	2130	6	2.00	0.700	FL(4)	P2(11)	0.050
0.9002	1749	3498	5247	6	2.00	0.800	FL(4)	P2(12)	0.050

Set(Set Number): Values
Eq(1): 0.167, 0.167, 0.167, 0.167, 0.167, 0.167
PD(2): 0.230, 0.130, 0.360, 0.100, 0.090, 0.090
LD(3): 0.286, 0.238, 0.190, 0.143, 0.095, 0.048
FL(4): 0.750, 0.050, 0.050, 0.050, 0.050, 0.050
P2(1): 0.250, 0.205, 0.170, 0.144, 0.124, 0.107
P2(2): 0.222, 0.194, 0.172, 0.153, 0.136, 0.123
P2(3): 0.200, 0.185, 0.171, 0.159, 0.148, 0.138
P2(4): 0.332, 0.152, 0.327, 0.073, 0.060, 0.056
P2(5): 0.299, 0.146, 0.340, 0.081, 0.068, 0.065
P2(6): 0.272, 0.141, 0.350, 0.088, 0.076, 0.073
P2(7): 0.400, 0.247, 0.159, 0.103, 0.062, 0.029
P2(8): 0.364, 0.247, 0.170, 0.114, 0.071, 0.034
P2(9): 0.333, 0.246, 0.179, 0.125, 0.079, 0.038
P2(10): 0.833, 0.036, 0.035, 0.033, 0.032, 0.031
P2(11): 0.811, 0.040, 0.039, 0.038, 0.037, 0.036
P2(12): 0.789, 0.044, 0.043, 0.042, 0.041, 0.040

Chart Section



PASS found the required sample sizes for the various cases. Note the large increase in sample size that occurs when the response probability of the first category is much larger than the rest.