

## Chapter 242

# Tests for Two Proportions in a Stratified Cluster-Randomized Design (Cochran-Mantel-Haenszel Test)

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### Introduction

This procedure calculates power and sample size for tests for two proportions in a stratified cluster randomized design in which the outcome variable is binary. It uses the results of Xu, Zhu, and Ahn (2019) which extends previous results to include varying cluster size. Although response rates may vary among strata, hypotheses about the overall odds ratio are tested with the Cochran-Mantel-Haenszel test.

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### Technical Details

The following discussion summarizes the results in Xu, Zhu, and Ahn (2019).

Suppose you are interested in comparing the disease response rates of two groups (treatment and control). Further suppose that response rate is known to be related to other covariates (such as age, race, or gender). It is often desirable to remove the covariate's impact from the comparison of the two proportions. This is accomplished by stratifying on the covariates and forming hypotheses about a common odds ratio across all clusters and strata. It is assumed that the data will be analyzed using the Cochran-Mantel-Haenszel test.

In this design, assume that the randomization is balanced with an equal number of clusters assigned to each of the two groups. We denote the treatment group as group 1 and the control group as group 2. Denote the number of clusters in each of the two groups in stratum  $k$  by  $J_k$ . The number of strata is denoted as  $K$ .

Let the cluster sizes be denoted by  $n_{1jk}$  and  $n_{2jk}$  where  $j$  is the cluster in stratum  $k$ . It is assumed that these cluster sizes are independently and identically distributed with means  $\mu_k$  and standard deviations  $\tau_k$ ,  $k = 1, \dots, K$ . The total number of subjects in the study is  $N = \sum_{k=1}^K \sum_{j=1}^{J_k} (n_{1jk} + n_{2jk})$ .

Let  $Y_{1ijk}$  and  $Y_{2ijk}$  be the binary outcome variable with possible values 0 or 1. Let  $\pi_{1k}$  and  $\pi_{2k}$  be the corresponding response probabilities for these variables in the treatment and control groups of the  $k^{\text{th}}$  stratum. Let  $p_{1k} = \left( \sum_{j=1}^{J_k} \sum_{i=1}^{n_{1jk}} Y_{1ijk} \right) / \left( \sum_{j=1}^{J_k} n_{1jk} \right)$  and  $p_{2k} = \left( \sum_{j=1}^{J_k} \sum_{i=1}^{n_{2jk}} Y_{2ijk} \right) / \left( \sum_{j=1}^{J_k} n_{2jk} \right)$  be the corresponding estimates of  $\pi_{1k}$  and  $\pi_{2k}$ .

## Tests for Two Proportions in a Stratified Cluster-Randomized Design (Cochran-Mantel-Haenszel Test)

Let  $\rho$  be the intraclass correlation coefficient (ICC) which is a measure of the similarity of subjects within the same cluster. Note that this correlation is assumed to be constant across all clusters.

Define the odds ratio between the treatment and control groups as

$$\psi_k = \frac{\frac{\pi_{1k}}{1 - \pi_{1k}}}{\frac{\pi_{2k}}{1 - \pi_{2k}}} = \frac{\pi_{1k}(1 - \pi_{2k})}{\pi_{2k}(1 - \pi_{1k})}$$

Further let  $\psi$  denote common odds ratio.

The task is to estimate the number of clusters needed for testing  $H_0: \psi = 1$  versus  $H_1: \psi \neq 1$  for a two-sided significance level  $\alpha$  and a power of  $1 - \beta$ .

The Cochran-Mantel-Haenszel statistic for testing the above hypothesis is

$$C = \frac{\sum_{k=1}^K w_k (p_{1k} - p_{2k})}{\sqrt{\sum_{k=1}^K w_k^2 [\text{Var}(p_{1k}) + \text{Var}(p_{2k})]}}$$

where

$$w_k = \frac{n_{1k}n_{2k}}{n_{1k} + n_{2k}}$$

$$n_{1k} = \sum_{j=1}^{J_k} n_{1jk}$$

$$n_{2k} = \sum_{j=1}^{J_k} n_{2jk}$$

The distribution of the statistic  $C$  is asymptotically standard normal.

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## Power Calculations

The following formulas for power use the quantities  $T$ ,  $U$ , and  $V$  which are defined as follows

$$T = \frac{1}{2} \sqrt{\sum_{k=1}^K f_k \left[ \rho \mu_k + \rho \frac{\tau_k^2}{\mu_k} + (1 - \rho) \right] \bar{\pi}_k (1 - \bar{\pi}_k)}$$

$$U = \sqrt{\frac{1}{8} \sum_{k=1}^K f_k \left[ \rho \mu_k + \rho \frac{\tau_k^2}{\mu_k} + (1 - \rho) \right] [\pi_{1k}(1 - \pi_{1k}) + \pi_{2k}(1 - \pi_{2k})]}$$

$$V = \frac{1}{4} \sum_{k=1}^K f_k (\pi_{1k} - \pi_{2k})$$

$$\bar{\pi}_k = (\pi_{1k} + \pi_{2k})/2$$

$$f_k = (n_{1k} + n_{2k})/N$$

$$\pi_{1k} = \frac{\psi \pi_{2k}}{1 - \pi_{2k} + \psi \pi_{2k}}$$

## Tests for Two Proportions in a Stratified Cluster-Randomized Design (Cochran-Mantel-Haenszel Test)

Three cases of statistical hypotheses are available. The power formula for each case is

1.  $H_0: \psi \geq 1$  versus  $H_1: \psi < 1$ .

$$\text{Power} = 1 - \beta = 1 - \Phi\left(\frac{V\sqrt{N} - Tz_{\alpha}}{U}\right)$$

2.  $H_0: \psi \leq 1$  versus  $H_1: \psi > 1$ .

$$\text{Power} = 1 - \beta = 1 - \Phi\left(\frac{-V\sqrt{N} + Tz_{1-\alpha}}{U}\right)$$

3.  $H_0: \psi = 1$  versus  $H_1: \psi \neq 1$ .

$$\text{Power} = 1 - \beta = 2 - \Phi\left(\frac{V\sqrt{N} - Tz_{\alpha/2}}{U}\right) - \Phi\left(\frac{-V\sqrt{N} + Tz_{1-\alpha/2}}{U}\right)$$

where  $\Phi(x)$  is the standard normal cumulative distribution function.

These power formulas are used to conduct a binary search for sample size or odds ratio.

## 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, refer to the Procedure Window chapter.

## Design Tab

The Design tab contain most of the parameters and options of interest for this procedure.

### Solve For

#### Solve For

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

### Test

#### Alternative Hypothesis

This option specifies whether a one-sided or two-sided hypothesis is analyzed.

*One-Sided* ( $H_1: OR < 1$ ) refers to a one-sided test in which the alternative hypothesis is of the form  $H_1: OR < 1$ .

*One-Sided* ( $H_1: OR > 1$ ) refers to a one-sided test in which the alternative hypothesis is of the form  $H_1: OR > 1$ .

*Two-Sided* ( $H_1: OR \neq 1$ ) refers to a two-sided test in which the alternative hypothesis is of the form  $H_1: OR \neq 1$ .

Note that the alternative hypothesis enters into power calculations by specifying the rejection region of the hypothesis test. Its accuracy is critical.

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## 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 equal proportions when in fact they are different.

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. For this procedure, a type-I error occurs when you reject the null hypothesis of equal group proportions when, in fact, they are equal.

Values must be between zero and one. Historically, an alpha value of 0.05 has been recommended for two-sided tests and 0.025 for one-sided tests. 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*.

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## Sample Size

### N (Sample Size)

Enter one or more values of N, the total number of subjects in the study. This parameter is the sum of the subjects in all clusters or strata. It is assumed that the number of treatment and control subjects is balanced in each stratum.

The N subjects are divided among the strata using the 'Percent of N in Each Stratum' setting.

### Example

Suppose that N is 1000 and three strata are used with 'Percent of N in Each Stratum' set to 25, 25, 50. The three stratum sample sizes would be 250, 250, and 500.

The number of clusters is based on this number and the 'Average of Cluster Sizes' settings.

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## Effect Size

### OR (Actual Odds Ratio)

Specify the odds ratio at which the power is to be calculated. The difference between this value and one represents the magnitude of the effect you wish to detect. This value is used with  $Pr(\text{Success})$  in the Control Group ( $P_2$ ) to calculate the  $Pr(\text{Success})$  in the treatment (intervention) group.

You may enter a range of values such as *0.5 0.6 0.7 0.8* or *1.25 to 2.0 by 0.25*.

The odds ratios must be greater than 0 and unequal to 1. Commonly, the odds ratio is between 0.25 and 4.0.

### ICC (Intracluster Correlation)

Enter a value for ICC, the intracluster correlation coefficient. This may be thought of as the correlation between any two observations in the same cluster. Xu, Zhu, and Ahn (2019) suggested estimating this parameter separately for each stratum-group and then averages these values to obtain a final estimate. They also mention obtaining confidence intervals for ICC from pilot (or previous) data.

Note that occasionally,  $ICC < 0$ . Since this is a correlation coefficient, it is possible for it to range from -1 to 1. You may enter a single value or a list of values, such as *0.01 0.02 0.03*.

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## Strata Information

### Cluster Size Variation Input

There are two ways in which you can specify the variation of the cluster sizes within a stratum. These are

- **Standard Deviation**

You will need to enter the population standard deviation of the cluster sizes within each stratum.

- **Coefficient of Variation**

You will need to enter the population coefficient of variation of the cluster sizes within each stratum.

### Set

This is an identification number used on the reports.

### Number of Strata

Specify the number of strata specified on this line. Usually, you will enter a “1” to specify a single stratum, or you will enter a “0” to ignore this line. However, this option lets you specify several strata that have the same parameter values.

The total number of strata is equal to the sum of these values.

### Examples

0 which means ‘ignore this line’.

1 which means ‘one stratum defined by this line’.

2 which means ‘two strata defined by this line’.

### Percent of N in Each Stratum

Enter the percentage that the number of subjects in a stratum is of the total number of subjects. If this line defines more than one stratum, this is the percentage FOR EACH stratum.

These percentages must sum to 100. If they don't, the program will adjust them so they do.

For example, suppose you enter two sets and specify a Number of Strata for both sets of 5. Further suppose that you enter 25 for the Percent of N in Each Stratum in both sets. The program would realize that there is a total of 10 strata in the experiment with an equal percentage of the total in each stratum. Thus, the individual percentages would be adjusted from 25 to 10.

Note that you should only enter one number, even if there are more than one stratum being defined by the line. These values can be any positive values. The values will be adjusted so that the percentages sum to 100.

### Average of Cluster Sizes

Enter the average cluster size of the clusters in a stratum in this set. This number applies to clusters in both the treatment and the control groups.

The value must be greater than or equal to 1.

### Standard Deviation of Cluster Sizes

Enter the population standard deviation of the cluster sizes in this set. This number applies to both the treatment and the control groups.

The values must be than or equal to zero.

### Example

Suppose the five cluster sizes in a stratum are 225, 314, 197, 266, and 248. The average cluster size is 250 and the population standard deviation (using  $N = 5$  in the denominator) is 39.4715.

**Tests for Two Proportions in a Stratified Cluster-Randomized Design (Cochran-Mantel-Haenszel Test)****Coefficient of Variation of Cluster Sizes**

Enter the coefficient of variation of the cluster sizes in this set. This number will apply to both the treatment and the control groups.

**Coefficient of Variation (CV)**

The coefficient of variation used here is the population standard deviation divided by the mean. It is used to calculate the standard deviation of the cluster sizes. It is often used because the standard deviation of cluster sizes is often roughly proportional to the cluster size mean.

The values must be greater than zero.

**Pr(Success) in the Control Group (P2)**

This is the probability that outcome of a subject in the CONTROL group in a stratum defined on this line will be positive (equal to one). In this procedure, it is labelled P2.

The success probability in the treatment group is calculated from this value using the common odds ratio. The relationship within a stratum is

$$OR = Odds(P1)/Odds(P2)$$

which, solving for P1, gives

$$P1 = (OR)P2 / (1 - P2 + (OR)P2).$$

Since this is a proportion, it must be between 0 and 1.

**Show More Strata Sets**

Check this box to show ten more Strata Information sets.

If this option is not checked, any active strata sets (Number of Strata > 0) with set identification numbers > 5 will be ignored.

## Example 1 – Finding Sample Size

A study is being planned to investigate the possible association between a certain drug and a certain disease. Since age is known to affect the disease rates, the population is stratified into four age groups with weights of 10%, 40%, 35%, and 15%. Furthermore, patients will be clustered by clinics. All patients in a clinic will receive either an intervention drug or a standard drug. The number of clinics receiving each treatment will be balanced.

Prior studies had shown the probability of this disease continuing after receiving the baseline treatment was 0.25, 0.20, 0.15, and 0.10, respectively, among the four age groups. The average number of patients per clinic has historically been 30, with a coefficient of variation of 0.4.

Two values of ICC will be used: 0.015 and 0.1. The significance level is set to 0.05 and the power is set to 0.8. The odds ratio is set to 1.5, 2, and 3.

### Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load this procedure. 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>
<b>Design Tab</b>	
Solve For .....	<b>Sample Size</b>
Alternative Hypothesis .....	<b>Two-Sided (H1: OR ≠ 1)</b>
Power .....	<b>0.8</b>
Alpha .....	<b>0.05</b>
OR (Actual Odds Ratio) .....	<b>1.5 2 3</b>
ICC (Intracluster Correlation) .....	<b>0.015 0.1</b>
Cluster Size Variation Input .....	<b>Coefficient of Variation</b>
Set 1 Number of Strata .....	<b>1</b>
Set 1 Percent of N in Each Stratum .....	<b>10</b>
Set 1 Average of Cluster Sizes .....	<b>30</b>
Set 1 Coefficient of Variation of Cluster Sizes .....	<b>0.4</b>
Set 1 Pr(Success) in the Control Group (P2) .....	<b>0.25</b>
Set 2 Number of Strata .....	<b>1</b>
Set 2 Percent of N in Each Stratum .....	<b>40</b>
Set 2 Average of Cluster Sizes .....	<b>30</b>
Set 2 Coefficient of Variation of Cluster Sizes .....	<b>0.4</b>
Set 2 Pr(Success) in the Control Group (P2) .....	<b>0.2</b>
Set 3 Number of Strata .....	<b>1</b>
Set 3 Percent of N in Each Stratum .....	<b>35</b>
Set 3 Average of Cluster Sizes .....	<b>30</b>
Set 3 Coefficient of Variation of Cluster Sizes .....	<b>0.4</b>
Set 3 Pr(Success) in the Control Group (P2) .....	<b>0.15</b>

**Tests for Two Proportions in a Stratified Cluster-Randomized Design (Cochran-Mantel-Haenszel Test)**

- Set 4 Number of Strata ..... **1**
- Set 4 Percent of N in Each Stratum..... **15**
- Set 4 Average of Cluster Sizes..... **30**
- Set 4 Coefficient of Variation of Cluster Sizes..... **0.4**
- Set 4 Pr(Success) in the Control Group (P2) ..... **0.1**
  
- Set 5 Number of Strata ..... **0**
- Show More Strata Sets..... **Unchecked**

## Annotated Output

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

### Numeric Results

**Numeric Results of the Cochran-Mantel-Haenszel Test**

Hypotheses: H0: OR = 1 vs. H1: OR ≠ 1  
 Number of Strata: 4

	Total Sample Size	Anticipated Number of Clusters	Actual Odds Ratio	Treatment Probability of Success	Control Probability of Success	Intracluster Correlation Coefficient	Alpha
Power	N	M	OR	P1	P2	ICC	
0.8000	1815	60.0	1.5000	0.2371	0.1725	0.0150	0.050
0.8000	5275	176.0	1.5000	0.2371	0.1725	0.1000	0.050
0.8000	578	20.0	2.0000	0.2919	0.1725	0.0150	0.050
0.8000	1681	56.0	2.0000	0.2919	0.1725	0.1000	0.050
0.8000	212	7.0	3.0000	0.3801	0.1725	0.0150	0.050
0.8000	617	20.0	3.0000	0.3801	0.1725	0.1000	0.050

**References**

Xu, X., Zhu, H., and Ahn, C. 2019. 'Sample size considerations for stratified cluster randomization design with binary outcomes and varying cluster size', *Statistics in Medicine*, Volume 38, Number 18, pages 3395-3404.  
 Donner, A. and Klar, N. 2000. *Design and Analysis of Cluster Randomization Trials in Health Research*. Arnold. London.  
 Nam, Jun-mo. 1992. 'Sample Size Determination for Case-Control Studies and the Comparison of Stratified and Unstratified Analyses,' *Biometrics*, Volume 48, pages 389-395.  
 Woolson, R.F., Bean, J.A., and Rojas, P.B. 1986. 'Sample Size for Case-Control Studies Using Cochran's Statistic,' *Biometrics*, Volume 42, pages 927-932.

**Report Definitions**

Power is the probability of rejecting a false null hypothesis. It should be close to one.  
 N is the total sample size, i.e., the total number of subjects summed across all strata.  
 M is the anticipated number of clusters. Half of these clusters are assigned to the treatment group, while the other half are assigned to the control group.  
 OR is the overall odds ratio, [Odds1] / [Odds2] assumed by the alternative hypothesis. This is the OR at which the power is computed.  
 P1 is the probability of a success in the treatment group. This is the weighted average of the individual P1's of all strata.  
 P2 is the probability of a success in the control group. This is the weighted average of the individual P2's of all strata.  
 ICC is the intracluster correlation coefficient. This is the correlation between any two responses within a particular stratum.  
 Alpha is the probability of rejecting a true null hypothesis.

**Summary Statements**

A stratified design, which divides the sample among 4 strata, is analyzed using the two-sided, Cochran-Mantel-Haenszel test. The total sample size of 1815 subjects, which is obtained from 60.0 clusters, achieves 80% power to reject an odds ratio of one assumed by the null hypothesis when the odds ratio is actually 1.5000. The significance level of the test was set at 0.050. Note that each cluster was completely allocated to either the treatment or control and that the number of treatment and control clusters was balanced within each stratum.

Tests for Two Proportions in a Stratified Cluster-Randomized Design (Cochran-Mantel-Haenszel Test)

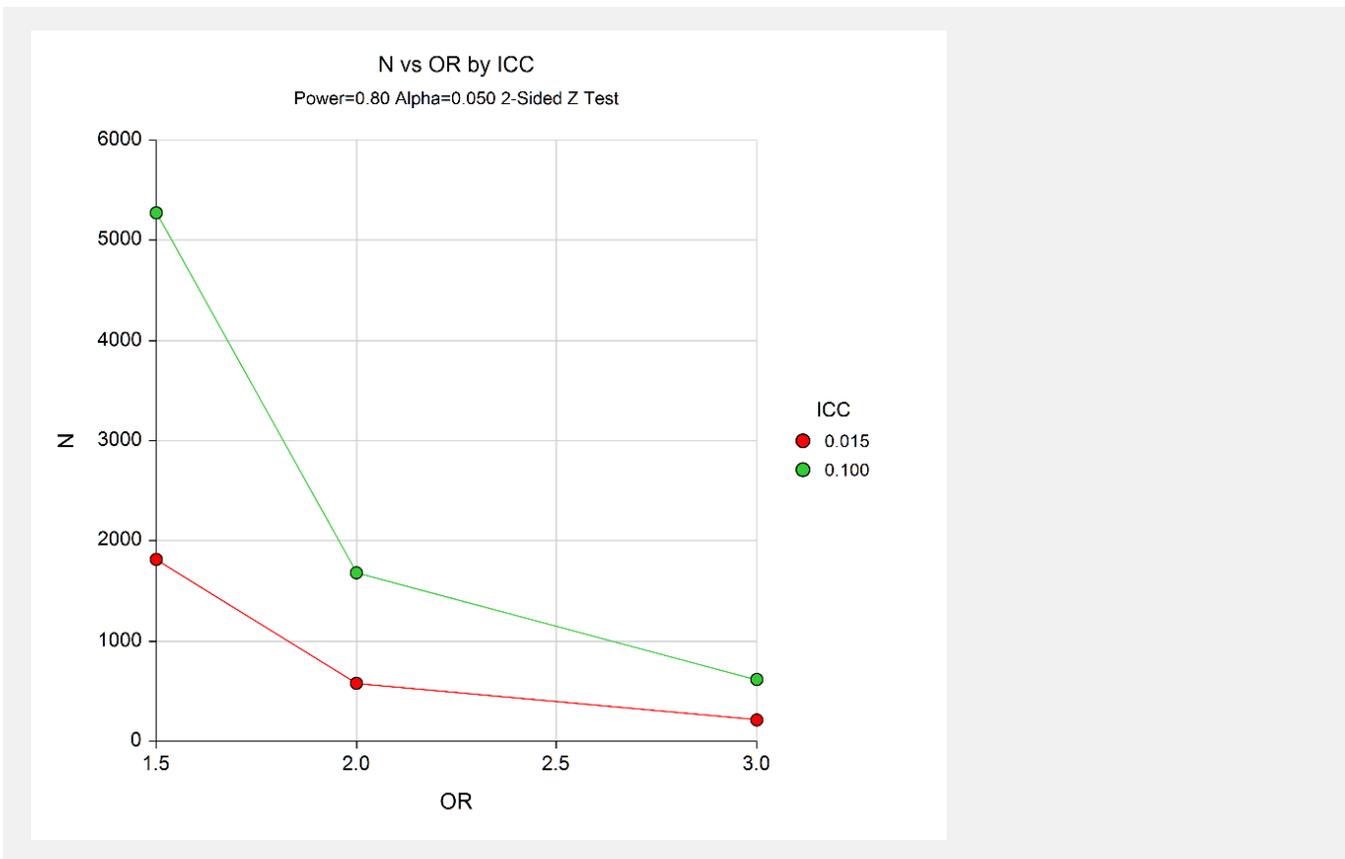
Strata-Detail Report

Set	Number of Strata	Percent of N in Each Stratum	Average of Cluster Sizes	Standard Deviation of Cluster Sizes	Coefficient of Variation of Cluster Sizes	Pr(Success) in the Control Group P2
1	1	10.00	30.0	12.00	0.4000	0.2500
2	1	40.00	30.0	12.00	0.4000	0.2000
3	1	35.00	30.0	12.00	0.4000	0.1500
4	1	15.00	30.0	12.00	0.4000	0.1000

**Strata-Detail Report Definitions**  
 Set is an identification number on the input screen.  
 Number of Strata is the number of strata defined by this set (input line).  
 Percent of N in Each Stratum is the percentage of the total sample size that is allocated to each stratum in this set.  
 Average of Cluster Sizes is the average cluster size (number of subjects) in each stratum of this set.  
 Standard Deviation of Cluster Sizes is the standard deviation of the cluster sizes in each stratum of this set.  
 Coefficient of Variation of Cluster Sizes is the coefficient of variation (SD/Mean) of the cluster sizes in each stratum of this set.  
 Pr(Success) in the Control Group P2 is the probability of a success in those clusters that are assigned to the control group in each stratum of this set.

This report shows the values of the individual, strata-level parameters that were used. These parameters are the same for all rows of the Numerical Results Report (shown above), so they are only displayed once.

Plots Section



The values from the Numerical Results report are displayed in this plot.

## Example 2 – Validation using Xu, Zhu, Ahn (2019)

Xu, Zhu, and Ahn (2019) provide an example of the power analysis of a stratified, cluster-randomized study. The data are to be analyzed by a two-sided Cochran-Mantel-Haenszel test. We will use their results to validate this procedure.

Their example had four strata with 4419, 4738, 4175, and 1093 subjects per stratum. (We will enter these numbers directly and let the program rescale them to percentages.)

The probability of success was 0.14 in each stratum. The average number of patients per cluster were 177, 119, 84, and 122. The corresponding standard deviations were 75, 53, 36, and 58.

The value of ICC was 0.015. The significance level is set to 0.05 and the power is set to 0.8. The odds ratio is set to 0.75923. They obtained a total sample size of 12387.

### Setup

This section presents the values of each of the parameters needed to run this example. First, from the PASS Home window, load this procedure. 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>
<b>Design Tab</b>	
Solve For .....	<b>Sample Size</b>
Alternative Hypothesis .....	<b>Two-Sided (H1: OR ≠ 1)</b>
Power.....	<b>0.8</b>
Alpha.....	<b>0.05</b>
OR (Actual Odds Ratio) .....	<b>0.75923</b>
ICC (Intracluster Correlation).....	<b>0.015</b>
Cluster Size Variation Input .....	<b>Standard Deviation</b>
Set 1 Number of Strata .....	<b>1</b>
Set 1 Percent of N in Each Stratum.....	<b>4419</b>
Set 1 Average of Cluster Sizes.....	<b>177</b>
Set 1 Standard Deviation of Cluster Sizes .....	<b>75</b>
Set 1 Pr(Success) in the Control Group (P2) .....	<b>0.14</b>
Set 2 Number of Strata .....	<b>1</b>
Set 2 Percent of N in Each Stratum.....	<b>4738</b>
Set 2 Average of Cluster Sizes.....	<b>119</b>
Set 2 Standard Deviation of Cluster Sizes .....	<b>53</b>
Set 2 Pr(Success) in the Control Group (P2) .....	<b>0.14</b>
Set 3 Number of Strata .....	<b>1</b>
Set 3 Percent of N in Each Stratum.....	<b>4175</b>
Set 3 Average of Cluster Sizes.....	<b>84</b>
Set 3 Standard Deviation of Cluster Sizes .....	<b>36</b>
Set 3 Pr(Success) in the Control Group (P2) .....	<b>0.14</b>

**Tests for Two Proportions in a Stratified Cluster-Randomized Design (Cochran-Mantel-Haenszel Test)**

Set 4 Number of Strata ..... **1**  
 Set 4 Percent of N in Each Stratum..... **1093**  
 Set 4 Average of Cluster Sizes..... **122**  
 Set 4 Standard Deviation of Cluster Sizes ..... **58**  
 Set 4 Pr(Success) in the Control Group (P2) ..... **0.14**

Set 5 Number of Strata ..... **0**  
 Show More Strata Sets..... **Unchecked**

**Output**

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

**Numeric Results with Continuity Correction**

**Numeric Results of the Cochran-Mantel-Haenszel Test** \_\_\_\_\_

Hypotheses: H0: OR = 1 vs. H1: OR ≠ 1  
 Number of Strata: 4

	Total Sample Size N	Anticipated Number of Clusters M	Actual Odds Ratio OR	Treatment Probability of Success P1	Control Probability of Success P2	Intracluster Correlation Coefficient ICC	Alpha
Power	12387	106.0	0.7592	0.1100	0.1400	0.0150	0.050

**Strata-Detail Report** \_\_\_\_\_

Set	Number of Strata	Percent of N in Each Stratum	Average of Cluster Sizes	Standard Deviation of Cluster Sizes	Coefficient of Variation of Cluster Sizes	Pr(Success) in the Control Group P2
1	1	30.63	177.0	75.00	0.4237	0.1400
2	1	32.85	119.0	53.00	0.4454	0.1400
3	1	28.94	84.0	36.00	0.4286	0.1400
4	1	7.58	122.0	58.00	0.4754	0.1400

PASS has also obtained a sample size of 12387, which validates this procedure.