

## Chapter 240

# Equivalence Tests for the Difference of Two Proportions in a Cluster-Randomized Design

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## Introduction

This module provides power analysis and sample size calculation for equivalence tests of the difference in two-sample, cluster-randomized designs in which the outcome is binary.

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## Technical Details

Our formulation comes from Donner and Klar (2000). Denote a binary observation by  $Y_{gkm}$  where  $g = 1$  or  $2$  is the group,  $k = 1, 2, \dots, K_g$  is a cluster within group  $g$ , and  $m = 1, 2, \dots, M_g$  is an individual in cluster  $k$  of group  $g$ . The results that follow assume an equal number of individuals per cluster. When the number of subjects from cluster to cluster are about the same, the power and sample size values should be fairly accurate. In these cases, the average number of subjects per cluster can be used.

The statistical hypothesis that is tested concerns the difference between the two group proportions,  $p_1$  and  $p_2$ . When necessary, we assume that group 1 is the treatment group and group 2 is the control group. With a simple modification, all of the large-sample sample size formulas that are listed in the module for testing two proportions can be used here.

When the individual subjects are randomly assigned to one of the two groups, the variance of the sample proportion is

$$\sigma_{S,g}^2 = \frac{p_g(1-p_g)}{n_g}$$

When the randomization is by clusters of subjects, the variance of the sample proportion is

$$\begin{aligned}\sigma_{C,g}^2 &= \frac{p_g(1-p_g)(1+(m_g-1)\rho)}{k_g m_g} \\ &= \sigma_{S,g}^2 [1+(m_g-1)\rho] \\ &= F_{g,\rho} \sigma_{S,g}^2\end{aligned}$$

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The factor  $\left[1 + (m_g - 1)\rho\right]$  is called the *inflation factor*. The Greek letter  $\rho$  is used to represent the *intracluster correlation coefficient (ICC)*. This correlation may be thought of as the simple correlation between any two subjects within the same cluster. If we stipulate that  $\rho$  is positive, it may also be interpreted as the proportion of total variability that is attributable to differences between clusters. This value is critical to the sample size calculation.

The asymptotic formulas that were used in comparing two proportions (see Chapter 213, “Equivalence Tests for the Difference Between Two Proportions”) may be used with cluster-randomized designs as well, as long as an adjustment is made for the inflation factor.

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### Power Calculations

A large sample approximation may be used that is most accurate when the values of  $n_1$  and  $n_2$  are large. The large approximation is made by replacing the values of  $\hat{p}_1$  and  $\hat{p}_2$  in the  $z$  statistic with the corresponding values of  $p_1$  and  $p_2$  under the alternative hypothesis, and then computing the results based on the normal distribution.

Note that in this case, exact calculations are not possible.

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### Procedure Options

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

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### Design Tab

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

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#### Solve For

##### Solve For

This option specifies the parameter to be solved for using the other parameters. The parameters that may be selected are *Power*, *Sample Size (K1)*, *Sample Size (M1)*, *Effect Size*, and *ICC*. Under most situations, you will select either *Power* or *Sample Size (K1)*.

Select *Sample Size (K1)* when you want to calculate the number of clusters per group needed to achieve a given power and alpha level.

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

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#### Test

##### Test Type

Specify which test statistic is used in searching and reporting. We recommend the likelihood score test.

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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.

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.

Values 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*.

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### Sample Size – Group 1 (Treatment)

#### K1 (Clusters in Group 1)

Enter a value (or range of values) for the number of clusters in this group. You may enter a range of values such as *10 to 20 by 2*. The sample size for this group is equal to the number of clusters times the number of subjects per cluster.

#### M1 (Items per Cluster in Group 1)

This is the average number of items (subjects) per cluster in group one. This value must be a positive number that is at least 1. You can use a list of values such as *100 150 200*.

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### Sample Size – Group 2 (Reference)

#### K2 (Clusters in Group 2)

This is the number of clusters in group two. The sample size for this group is equal to the number of clusters times the number of subjects per cluster. This value must be a positive number.

If you simply want a multiple of the value for group one, you would enter the multiple followed by *K1*, with no blanks. If you want to use *K1* directly, you do not have to pre-multiply by 1. For example, all of the following are valid entries: *10 K1 2K1 0.5K1*.

You can use a list of values such as *10 20 30* or *K1 2K1 3K1*.

#### M2 (Items per Cluster in Group 2)

This is the number of items (subjects) per cluster in group two. This value must be a positive number.

If you simply want a multiple of the value for group one, you would enter the multiple followed by *M1*, with no blanks. If you want to use *M1* directly, you do not have to pre-multiply by 1. For example, all of the following are valid entries: *10 M1 2M1 0.5M1*.

You can use a list of values such as *10 20 30* or *M1 2M1 3M1*.

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### Effect Size

#### Input Type

Indicate what type of values to enter to specify the differences. Regardless of the entry type chosen, the test statistics used in the power and sample size calculations are the same. This option is simply given for convenience in specifying the differences.

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#### Effect Size – Equivalence Differences (P1.0 – P2)

*Only displayed if Input Type = “Differences”*

##### D0.U & D0.L (Upper & Lower Equivalence Difference)

Specify the *margin of equivalence* by specifying the largest distance above (D0.U) and below (D0.L) P2 which will still result in the conclusion of equivalence. As long as the actual difference is between these two values, the difference is not large enough to be of practical importance.

The values of D0.U must be positive and the values of D0.L must be negative. D0.L can be set to ‘-D0.U,’ which is usually what is desired.

The power calculations assume that P1.0 is the value of the P1 under the null hypothesis. This value is used with P2 to calculate the value of P1.0 using the formula:  $P1.0U = D0.U + P2$ .

You may enter a range of values for D0.U such as *.03 .05 .10* or *.05 to .20 by .05*.

Note that if you enter values for D0.L (other than '-D0.U'), they are used in pairs with the values of D0.U. Thus, the first values of D0.U and D0.L are used together, then the second values of each are used, and so on.

D0.L must be between -1 and 0. D0.U must be between 0 and 1. Neither can take on the values -1, 0, or 1.

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#### Effect Size – Actual Difference (P1.1 – P2)

*Only displayed if Input Type = “Differences”*

##### D1 (Actual Difference)

This option specifies the actual difference between P1.1 (the actual value of P1) and P2. This is the value of the difference at which the power is calculated. In equivalence trials, this difference is often set to zero.

The power calculations assume that P1.1 is the actual value of the proportion in group 1 (experimental or treatment group). This difference is used with P2 to calculate the true value of P1 using the formula:  $P1.1 = D1 + P2$ .

You may enter a range of values such as *-.05 0 .5* or *-.05 to .05 by .02*. Actual differences must be between -1 and 1. They cannot take on the values -1 or 1.

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#### Effect Size – Equivalence Proportions (Group 1)

*Only displayed if Input Type = “Proportions”*

##### P1.0U & P1.0L (Upper & Lower Equivalence Proportions)

Specify the *margin of equivalence* directly by giving the upper and lower bounds of P1.0. The two groups are assumed to be equivalent when P1.0 is between these values. Thus, P1.0U should be greater than P2 and P1.0L should be less than P2.

Note that the values of P1.0U and P1.0L are used in pairs. Thus, the first values of P1.0U and P1.0L are used together, and then the second values of each are used, and so on.

You may enter a range of values such as *0.03 0.05 0.10* or *0.01 to 0.05 by 0.01*.

Proportions must be between 0 and 1. They cannot take on the values 0 or 1. These values should surround P2.

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### Effect Size – Actual Proportion (Group 1)

*Only displayed if Input Type = “Proportions”*

#### P1.1 (Actual Proportion)

This option specifies the value of P1.1, which is the value of the treatment proportion at which the power is to be calculated. Proportions must be between 0 and 1. They cannot take on the values 0 or 1.

You may enter a range of values such as *0.03 0.05 0.10* or *0.01 to 0.05 by 0.01*.

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### Effect Size – Group 2 (Reference)

#### P2 (Group 2 Proportion)

Specify the value of P2, the control, baseline, or standard group’s proportion. The null hypothesis is that the two proportions differ by a specified amount (See *Specify Group 1 Proportion using* below).

Since P2 is a proportion, these values must be between 0 and 1.

You may enter a range of values such as *0.1 0.2 0.3* or *0.1 to 0.9 by 0.1*.

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### Effect Size – Intracluster Correlation

#### ICC (Intracluster Correlation)

Enter a value (or range of values) for the intracluster correlation. This correlation may be thought of as the simple correlation between any two observations in the same cluster. It may also be thought of as the proportion of total variance in the observations that can be attributed to difference between clusters.

Although the actual range for this value is from 0 to 1, typical values range from 0.002 to 0.05.

## Example 1 – Finding Power

A study is being designed to establish the equivalence of a new treatment compared to the current treatment. Historically, the standard treatment has enjoyed a 60% cure rate. The new treatment reduces the seriousness of certain side effects that occur with the standard treatment. Thus, the new treatment will be adopted even if it is slightly less effective than the standard treatment. The researchers will recommend adoption of the new treatment if its cure rate is within 0.15 of the standard treatment.

The researchers will recruit patients from various hospitals. All patients at a particular hospital will receive the same treatment. They anticipate enlisting an average of 50 patients per hospital. Based on similar studies, they estimate the intraclass correlation to be 0.002.

The researchers plan to use the Farrington and Manning likelihood score test statistic to analyze the data. They want to study the power of the two, one-sided tests proposed by Farrington and Manning when the number of clusters per groups ranges from 2 to 10. They want to investigate the behavior of this test when the actual cure rate of the new treatment ranges from 60% to 66%. The significance level will be 0.05.

## 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 of Two Proportions in a Cluster-Randomized Design** procedure window by expanding **Proportions**, then **Two Proportions (Cluster-Randomized)**, then clicking on **Equivalence**, and then clicking on **Equivalence Tests for the Difference of Two Proportions in a Cluster-Randomized Design**. 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>Power</b>
Test Type .....	<b>Likelihood Score (Farr. &amp; Mann.)</b>
Alpha .....	<b>0.05</b>
K1 (Clusters in Group 1) .....	<b>2 4 6 8 10</b>
M1 (Items per Cluster in Group 1) .....	<b>50</b>
K2 (Clusters in Group 2) .....	<b>K1</b>
M2 (Items per Cluster in Group 2) .....	<b>M1</b>
Input Type .....	<b>Differences</b>
D0.U (Upper Equivalence Difference) ....	<b>0.15</b>
D0.L (Lower Equivalence Difference) .....	<b>-D0.U</b>
D1 (Actual Difference) .....	<b>0 0.03 0.06</b>
P2 (Group 2 Proportion) .....	<b>0.6</b>
ICC (Intraclass Correlation) .....	<b>0.002</b>

## Equivalence Tests for the Difference of Two Proportions in a Cluster-Randomized Design

## Output

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

## Numeric Results

## Numeric Results

Test Statistic: Likelihood Score Test (Farrington & Manning)

Hypotheses:  $H_0: P_1 - P_2 \leq D_{0.L}$  or  $P_1 - P_2 \geq D_{0.U}$  vs.  $H_1: D_{0.L} < P_1 - P_2 < D_{0.U}$

Power	Group 1 Clusters/ Items K1/M1	Group 2 Clusters/ Items K2/M2	Grp 2 Prop P2	Grp 1 Lower Equiv. Prop P1.0L	Grp 1 Upper Equiv. Prop P1.0U	Grp 1 Actual Prop P1.1	Lower Equiv. Diff D0.L	Upper Equiv. Diff D0.U	Actual Diff D1	Intra- Cluster Corr. ICC	Alpha
0.33835	2/50	2/50	0.6000	0.4500	0.7500	0.6000	-0.1500	0.1500	0.0000	0.0020	0.050
0.80415	4/50	4/50	0.6000	0.4500	0.7500	0.6000	-0.1500	0.1500	0.0000	0.0020	0.050
0.94885	6/50	6/50	0.6000	0.4500	0.7500	0.6000	-0.1500	0.1500	0.0000	0.0020	0.050
0.98771	8/50	8/50	0.6000	0.4500	0.7500	0.6000	-0.1500	0.1500	0.0000	0.0020	0.050
0.99722	10/50	10/50	0.6000	0.4500	0.7500	0.6000	-0.1500	0.1500	0.0000	0.0020	0.050
0.32109	2/50	2/50	0.6000	0.4500	0.7500	0.6300	-0.1500	0.1500	0.0300	0.0020	0.050
0.73719	4/50	4/50	0.6000	0.4500	0.7500	0.6300	-0.1500	0.1500	0.0300	0.0020	0.050
0.89163	6/50	6/50	0.6000	0.4500	0.7500	0.6300	-0.1500	0.1500	0.0300	0.0020	0.050
0.95510	8/50	8/50	0.6000	0.4500	0.7500	0.6300	-0.1500	0.1500	0.0300	0.0020	0.050
0.98181	10/50	10/50	0.6000	0.4500	0.7500	0.6300	-0.1500	0.1500	0.0300	0.0020	0.050
0.25939	2/50	2/50	0.6000	0.4500	0.7500	0.6600	-0.1500	0.1500	0.0600	0.0020	0.050
0.55419	4/50	4/50	0.6000	0.4500	0.7500	0.6600	-0.1500	0.1500	0.0600	0.0020	0.050
0.70910	6/50	6/50	0.6000	0.4500	0.7500	0.6600	-0.1500	0.1500	0.0600	0.0020	0.050
0.81306	8/50	8/50	0.6000	0.4500	0.7500	0.6600	-0.1500	0.1500	0.0600	0.0020	0.050
0.88235	10/50	10/50	0.6000	0.4500	0.7500	0.6600	-0.1500	0.1500	0.0600	0.0020	0.050

## Report Definitions

Power is the probability of rejecting a false null hypothesis. It should be close to one.

K1 and K2 are the number of clusters in groups 1 and 2, respectively.

M1 and M2 are the average number of items (subjects) per cluster in groups 1 and 2, respectively.

P2 is the proportion for group 2, the standard, reference, baseline, or control group.

P1.0L is the smallest proportion for group 1 (treatment group) that still results in the conclusion of equivalence.

P1.0U is the largest proportion for group 1 (treatment group) that still results in the conclusion of equivalence.

$D_{0.L} = P_{1.0L} - P_2$  is the lower bound on the difference that results in the conclusion of equivalence.

$D_{0.U} = P_{1.0U} - P_2$  is the upper bound on the difference that results in the conclusion of equivalence.

$D_1 = P_{1.1} - P_2$  is the actual difference at which the power is calculated.

ICC is the intraclass correlation.

Alpha is the probability of rejecting a true null hypothesis.

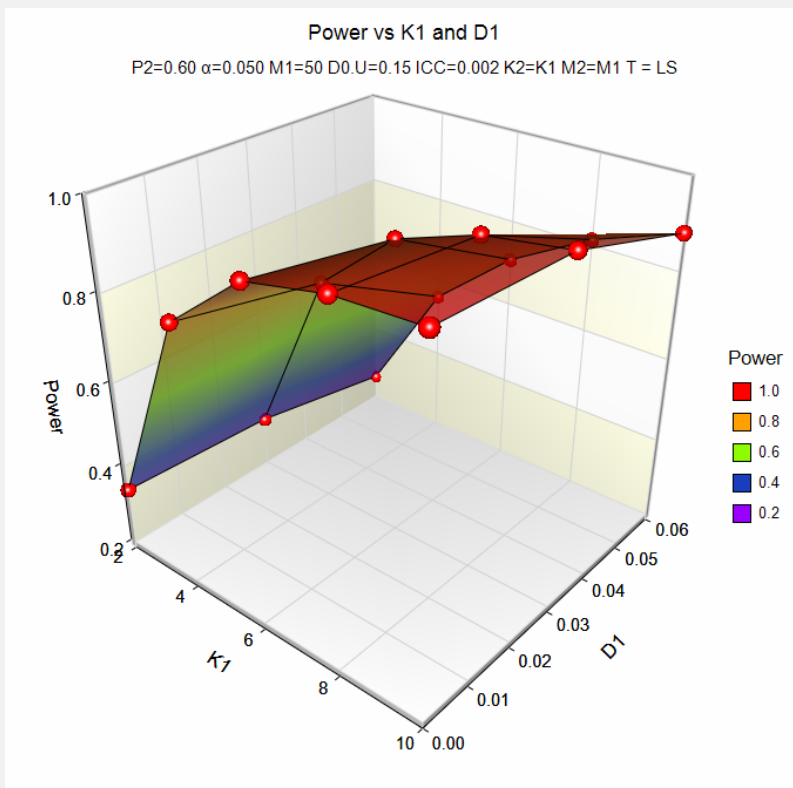
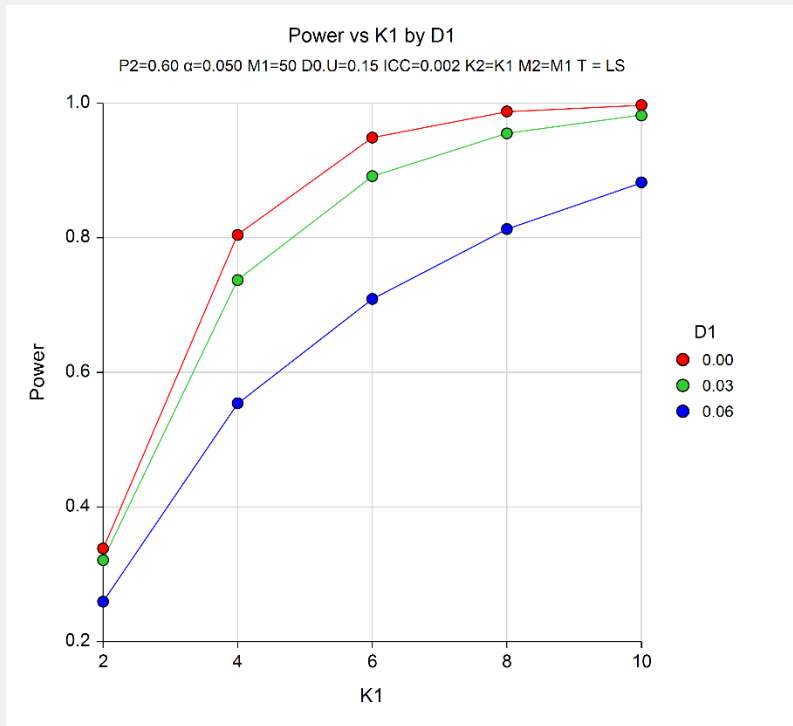
## Summary Statements

Sample sizes of 100 in group 1 and 100 in group 2, which were obtained by sampling 2 clusters with 50 subjects each in group 1 and 2 clusters with 50 subjects each in group 2, achieve 33.835% power to detect equivalence. The margin of equivalence, given in terms of the difference between the proportions, extends from -0.1500 to 0.1500. The actual difference between the proportions is 0.0000. The group 2 proportion is 0.6000. The calculations assume that two, one-sided Likelihood Score Tests (Farrington & Manning) were used. The intraclass correlation is 0.0020, and the significance level of the test is 0.050.

This report shows the values of each of the parameters, one scenario per row. The total number of items sampled in group 1 is  $N_1 = K_1 \times M_1$ . The total number of items sampled in group 2 is  $N_2 = K_2 \times M_2$ .

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Plots Section



The values from the table are displayed on the above charts. These charts give a quick look at the sample size that will be required for various values of D1.



## Example 2 – Finding the Sample Size (Number of Clusters)

Continuing with the scenario given in Example 1, the researchers want to determine the number of clusters necessary for each value of D1 when the target power is set to 0.80.

### 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 of Two Proportions in a Cluster-Randomized Design** procedure window by expanding **Proportions**, then **Two Proportions (Cluster-Randomized)**, then clicking on **Equivalence**, and then clicking on **Equivalence Tests for the Difference of Two Proportions in a Cluster-Randomized Design**. 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 (K1)</b>
Test Type.....	<b>Likelihood Score (Farr. &amp; Mann.)</b>
Power.....	<b>0.80</b>
Alpha.....	<b>0.05</b>
M1 (Items per Cluster in Group 1) .....	<b>50</b>
K2 (Clusters in Group 2).....	<b>K1</b>
M2 (Items per Cluster in Group 2) .....	<b>M1</b>
Input Type.....	<b>Differences</b>
D0.U (Upper Equivalence Difference) ....	<b>0.15</b>
D0.L (Lower Equivalence Difference).....	<b>-D0.U</b>
D1 (Actual Difference) .....	<b>0 0.03 0.06</b>
P2 (Group 2 Proportion) .....	<b>0.6</b>
ICC (Intracluster Correlation).....	<b>0.002</b>

### Output

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

### Numeric Results

<b>Numeric Results</b>											
Test Statistic: Likelihood Score Test (Farrington & Manning)											
Hypotheses: H0: P1 - P2 ≤ D0.L or P1 - P2 ≥ D0.U vs. H1: D0.L < P1 - P2 < D0.U											
	Group 1 Clusters/ Items	Group 2 Clusters/ Items	Grp 2 Prop P2	Grp 1 Lower Equiv. Prop P1.0L	Grp 1 Upper Equiv. Prop P1.0U	Grp 1 Actual Prop P1.1	Lower Equiv. Diff D0.L	Upper Equiv. Diff D0.U	Actual Diff D1	Intra- Cluster Corr. ICC	Alpha
Power	K1/M1	K2/M2	P2	P1.0L	P1.0U	P1.1	D0.L	D0.U	D1	ICC	Alpha
0.80415	4/50	4/50	0.6000	0.4500	0.7500	0.6000	-0.1500	0.1500	0.0000	0.0020	0.050
0.83188	5/50	5/50	0.6000	0.4500	0.7500	0.6300	-0.1500	0.1500	0.0300	0.0020	0.050
0.81306	8/50	8/50	0.6000	0.4500	0.7500	0.6600	-0.1500	0.1500	0.0600	0.0020	0.050

The required sample size depends a great deal on the value of D1. The researchers should spend time determining the most appropriate value for D1.

## Example 3 – Finding Power after an Experiment

Individuals promoting a new, more expensive treatment claim that it achieves better results than the current treatment without citing statistical evidence. A group of researchers attempted to show the claim was false through a study involving 12 hospitals. Two hundred patients at each of 6 randomly chosen hospitals were given the current treatment. Two hundred patients at each of the remaining 6 hospitals were given the new treatment. It was agreed before the experiment that if a difference of less than 0.05 in proportion of success could be shown, the two treatments would be deemed equivalent. The proportion of patients responding properly to the current treatment was  $540/1200 = 0.450$ . The proportion of patients responding properly to the new treatment was  $570/1200 = 0.475$ . This result did not show significant equivalence at the 0.05 level. The researchers want to know the power of their equivalence test. They decide to use the intraclass correlation coefficient estimated from the data, which was 0.0043. Although the observed difference in proportions is  $0.475 - 0.450 = 0.025$ , the equivalence difference is still 0.05. This value is used in the power calculation.

### 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 of Two Proportions in a Cluster-Randomized Design** procedure window by expanding **Proportions**, then **Two Proportions (Cluster-Randomized)**, then clicking on **Equivalence**, and then clicking on **Equivalence Tests for the Difference of Two Proportions in a Cluster-Randomized Design**. 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>
<b>Design Tab</b>	
Solve For .....	<b>Power</b>
Test Type .....	<b>Likelihood Score (Farr. &amp; Mann.)</b>
Alpha .....	<b>0.05</b>
K1 (Clusters in Group 1) .....	<b>6</b>
M1 (Items per Cluster in Group 1) .....	<b>200</b>
K2 (Clusters in Group 2) .....	<b>K1</b>
M2 (Items per Cluster in Group 2) .....	<b>M1</b>
Input Type .....	<b>Differences</b>
D0.U (Upper Equivalence Difference) ....	<b>0.05</b>
D0.L (Lower Equivalence Difference) .....	<b>-D0.U</b>
D1 (Actual Difference) .....	<b>0.0</b>
P2 (Group 2 Proportion) .....	<b>0.45</b>
ICC (Intraclass Correlation) .....	<b>0.0043</b>

## Equivalence Tests for the Difference of Two Proportions in a Cluster-Randomized Design

### Output

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

### Numeric Results

Numeric Results											
Test Statistic: Likelihood Score Test (Farrington & Manning)											
Hypotheses: $H_0: P_1 - P_2 \leq D_{0.L}$ or $P_1 - P_2 \geq D_{0.U}$ vs. $H_1: D_{0.L} < P_1 - P_2 < D_{0.U}$											
Power	Group 1 Clusters/ Items	Group 2 Clusters/ Items	Grp 2 Prop P2	Grp 1 Lower Equiv. Prop P1.0L	Grp 1 Upper Equiv. Prop P1.0U	Grp 1 Actual Prop P1.1	Lower Equiv. Diff D0.L	Upper Equiv. Diff D0.U	Actual Diff D1	Intra- Cluster Corr. ICC	Alpha
0.13053	6/200	6/200	0.4500	0.4000	0.5000	0.4500	-0.0500	0.0500	0.0000	0.0043	0.050

The power of the test of equivalence was only 0.1305.

### Example 4 – Finding Sample Size (Individuals within Clusters)

An agency would like to show the proportion of success is the same for two treatments. Eight doctors are available for the study. Four will be randomly chosen to be trained to administer treatment 1. The remaining four will administer treatment 2. The treatments will be considered equivalent if the proportion of success of treatment 1 is within 0.10 of treatment 2 success. The agency would like to know the number of patients that need to be treated by each doctor to achieve 80% power for the equivalence test. Various values for the intracluster correlation coefficient will be used since its true value is unknown. It is expected that the two treatments will have a success rate near 0.70. Alpha is set at 0.05.

### 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 of Two Proportions in a Cluster-Randomized Design** procedure window by expanding **Proportions**, then **Two Proportions (Cluster-Randomized)**, then clicking on **Equivalence**, and then clicking on **Equivalence Tests for the Difference of Two Proportions in a Cluster-Randomized Design**. 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>
<b>Design Tab</b>	
Solve For .....	<b>Sample Size (M1)</b>
Test Type .....	<b>Likelihood Score (Farr. &amp; Mann.)</b>
Power .....	<b>0.80</b>
Alpha .....	<b>0.05</b>
K1 (Clusters in Group 1) .....	<b>4</b>
K2 (Clusters in Group 2) .....	<b>K1</b>
M2 (Items per Cluster in Group 2) .....	<b>M1</b>
Input Type .....	<b>Differences</b>
D0.U (Upper Equivalence Difference) ....	<b>0.1</b>
D0.L (Lower Equivalence Difference) .....	<b>-D0.U</b>
D1 (Actual Difference) .....	<b>0.0</b>
P2 (Group 2 Proportion) .....	<b>0.7</b>
ICC (Intracluster Correlation) .....	<b>0.001 to 0.01 by 0.001</b>

Equivalence Tests for the Difference of Two Proportions in a Cluster-Randomized Design

Output

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

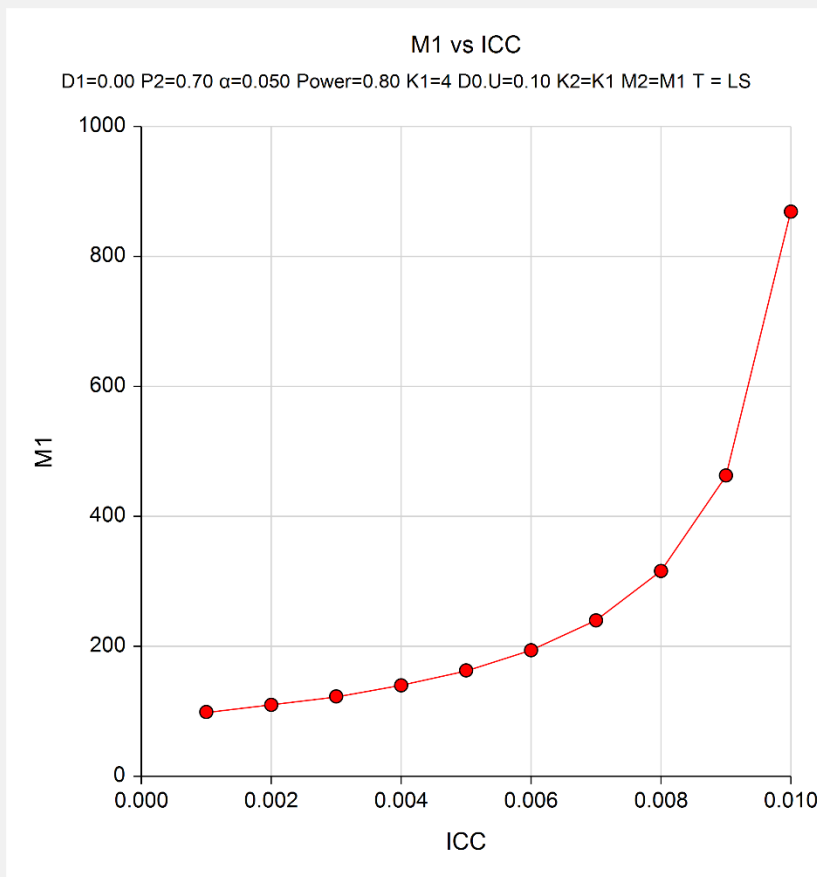
Numeric Results

Numeric Results

Test Statistic: Likelihood Score Test (Farrington & Manning)

Hypotheses:  $H_0: P_1 - P_2 \leq D_{0.L}$  or  $P_1 - P_2 \geq D_{0.U}$  vs.  $H_1: D_{0.L} < P_1 - P_2 < D_{0.U}$

Power	Group 1 Clusters/ Items K1/M1	Group 2 Clusters/ Items K2/M2	Grp 2 Prop P2	Grp 1 Lower Equiv. Prop P1.0L	Grp 1 Upper Equiv. Prop P1.0U	Grp 1 Actual Prop P1.1	Lower Equiv. Diff D0.L	Upper Equiv. Diff D0.U	Actual Diff D1	Intra-Cluster Corr. ICC	Alpha
0.80228	4/99	4/99	0.7000	0.6000	0.8000	0.7000	-0.1000	0.1000	0.0000	0.0010	0.050
0.80312	4/110	4/110	0.7000	0.6000	0.8000	0.7000	-0.1000	0.1000	0.0000	0.0020	0.050
0.80160	4/123	4/123	0.7000	0.6000	0.8000	0.7000	-0.1000	0.1000	0.0000	0.0030	0.050
0.80121	4/140	4/140	0.7000	0.6000	0.8000	0.7000	-0.1000	0.1000	0.0000	0.0040	0.050
0.80167	4/163	4/163	0.7000	0.6000	0.8000	0.7000	-0.1000	0.1000	0.0000	0.0050	0.050
0.80077	4/194	4/194	0.7000	0.6000	0.8000	0.7000	-0.1000	0.1000	0.0000	0.0060	0.050
0.80014	4/240	4/240	0.7000	0.6000	0.8000	0.7000	-0.1000	0.1000	0.0000	0.0070	0.050
0.80006	4/316	4/316	0.7000	0.6000	0.8000	0.7000	-0.1000	0.1000	0.0000	0.0080	0.050
0.80001	4/463	4/463	0.7000	0.6000	0.8000	0.7000	-0.1000	0.1000	0.0000	0.0090	0.050
0.80006	4/869	4/869	0.7000	0.6000	0.8000	0.7000	-0.1000	0.1000	0.0000	0.0100	0.050



The number of patients needed to be treated by each doctor ranges from 99 to 869 depending on the value of the intracluster correlation coefficient.

## Example 5 – Validation

We could not find an example of this type of analysis in the literature. Therefore, we will validate the procedure by comparing the results to those computed by the “Equivalence Tests for the Difference Between Two Proportions” procedure since both should give identical results for the same sample sizes when the ICC is set to zero. We ran the case when  $N_1 = N_2 = 200$ ,  $P_2 = 0.6$ ,  $D_0.U = 0.15$ ,  $D_0.L = -D_0.U$ ,  $D_1 = 0$ , and  $\text{Alpha} = 0.05$ . In this procedure, set  $M_1 = 1$  and set  $K_1 = 200$ . The Equivalence Tests for the Difference Between Two Proportions procedure calculates the power to be 0.84823 for the Likelihood Score (Farrington & Manning) 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 **Equivalence Tests for the Difference of Two Proportions in a Cluster-Randomized Design** procedure window by expanding **Proportions**, then **Two Proportions (Cluster-Randomized)**, then clicking on **Equivalence**, and then clicking on **Equivalence Tests for the Difference of Two Proportions in a Cluster-Randomized Design**. You may then make the appropriate entries as listed below, or open **Example 5** by going to the **File** menu and choosing **Open Example Template**.

<u>Option</u>	<u>Value</u>
<b>Design Tab</b>	
Solve For .....	<b>Power</b>
Test Type .....	<b>Likelihood Score (Farr. &amp; Mann.)</b>
Alpha .....	<b>0.05</b>
K1 (Clusters in Group 1) .....	<b>200</b>
M1 (Items per Cluster in Group 1) .....	<b>1</b>
K2 (Clusters in Group 2) .....	<b>K1</b>
M2 (Items per Cluster in Group 2) .....	<b>M1</b>
Input Type .....	<b>Differences</b>
D0.U (Upper Equivalence Difference) ....	<b>0.15</b>
D0.L (Lower Equivalence Difference) .....	<b>-D0.U</b>
D1 (Actual Difference) .....	<b>0</b>
P2 (Group 2 Proportion) .....	<b>0.6</b>
ICC (Intracluster Correlation) .....	<b>0.0</b>

### Output

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

#### Numeric Results

<b>Numeric Results</b>											
Test Statistic: Likelihood Score Test (Farrington & Manning)											
Hypotheses: $H_0: P_1 - P_2 \leq D_0.L \text{ or } P_1 - P_2 \geq D_0.U$ vs. $H_1: D_0.L < P_1 - P_2 < D_0.U$											
	Group 1 Clusters/ Items	Group 2 Clusters/ Items	Grp 2 Prop P2	Grp 1 Lower Equiv. Prop P1.0L	Grp 1 Upper Equiv. Prop P1.0U	Grp 1 Actual Prop P1.1	Lower Equiv. Diff D0.L	Upper Equiv. Diff D0.U	Actual Diff D1	Intra- Cluster Corr. ICC	Alpha
<b>Power</b>	<b>0.84823</b>	200/1	200/1	0.6000	0.4500	0.7500	0.6000	-0.1500	0.1500	0.0000	0.050

The power computed by this procedure is also 0.84823 when  $\text{ICC} = 0$ .