Chapter 566

Equivalence Tests for One-Way Analysis of Variance Assuming Equal Variances

Introduction

This procedure computes power and sample size of equivalence tests of the means of two or more groups which are analyzed using a noncentral F-test. The results in this chapter come from Shieh (2016), Jan and Shieh (2019), and Wellek (2010).

Technical Details for the One-Way ANOVA Equivalence Test

Suppose *G* groups each have a normal distribution and with means $\mu_1, \mu_2, \ldots, \mu_G$ and common variance σ^2. Let $n_1, n_2, \ldots, n_G$ denote the sample size of each group and let *N* denote the total sample size of all groups. The multigroup equivalence problem requires one to show that the means are sufficiently close to each other. Wellek (2010) accomplished this by defining a set of equivalence means, $\mu_{01}, \mu_{02}, \ldots, \mu_{0G}$, that are as far apart as possible and still be termed equivalent. He then summarized the means using their weighted variance

$$\sigma_{m0}^2 = \sum_{i=1}^{G} \left(\frac{n_i}{N}\right) (\mu_{0i} - \bar{\mu}_0)^2$$

The corresponding variance of the group means under the alternative hypothesis is given by

$$\sigma_{m1}^2 = \sum_{i=1}^{G} \left(\frac{n_i}{N}\right) (\mu_{1i} - \bar{\mu}_1)^2$$

where $\bar{\mu}_1$ is the weighted mean

$$\bar{\mu}_1 = \sum_{i=1}^{G} \left(\frac{n_i}{N}\right) \mu_{1i}$$

Given the above terminology, Wellek (2010) and Shieh (2016) suggested testing the hypothesis of mean equivalence using

$$H_0: f \geq f_0 \quad \text{versus} \quad H_1: f < f_0$$

where f^2 represents the usual F-test from a one-way design and $f_0^2 = \sigma_{m0}^2/\sigma^2$ is the equivalence bound defined above.

Under H_0, the usual F statistic, denoted F^*, is assumed to follow the noncentral F distribution

$$F^* \sim F'_{G-1,N-G,\Lambda_0}$$

where $\Lambda_0 = Nf_0^2$. Note that Λ_0 does not depend on data. Rather, it depends on the user specified set of equivalence values.

The value of F^* is given by

$$F^* = \frac{SSM/(G-1)}{SSE/(N-G)}$$

where *SSM* is the sum of squares of treatment means and *SSE* is the sum of squares of error.

The null hypothesis is rejected at the significance level α if $F^* < F'_{1-\alpha,G-1,N-G,\Lambda_0}$.

The power function of this test statistic at a particular set of means is given by

$$\text{Power} = \Pr\left[F'_{G-1,N-G,\Lambda_1} < F'_{1-\alpha,G-1,N-G,\Lambda_0}\right]$$

where $\Lambda_1 = Nf_1^2$ and $f_1^2 = \sigma_{m1}^2/\sigma^2$. This can easily be computed using our noncentral *F* cumulative distribution function. You have to be careful that $\sigma_{m1}^2 < \sigma_{m0}^2$.

If a sample size is desired, it can be determined using a standard binary search algorithm.

Example 1 – Finding Power

An experiment is being designed to assess the equivalence of the means of four groups using a noncentral *F* test with a significance level of 0.05. Previous studies have shown that the standard deviation is about 2. The variation allowed in equivalent means is represented by the values {5, 5, 7, 7}. Treatment means of {5, 5, 6, 6} represent the alternative hypothesis. To better understand the relationship between power and sample size, the researcher wants to compute the power for several group sample sizes between 10 and 70. The sample sizes will be equal across all groups.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 1** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab

Solve For .... **Power**
Alpha... **0.05**
G (Number of Groups) **4**
Group Allocation Input Type .... **Equal to ni (Sample Size per Group)**
ni (Sample Size per Group) **10 20 30 40 50 60 70**
μ0 Input Type.. **Enter μ0 (Group Means|H0)**
μ0 (Group Means|H0) **5 5 7 7**
μ1 Input Type.. **Enter μ1 (Group Means|H1)**
μ1 (Group Means|H1) **5 5 6 6**
σ (Standard Deviation).................................. **2**

Output

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

Numeric Reports

Numeric Results

Solve For: Power
Number of Groups: 4

	Sample Size		Group Means H0 (Equiv. Boundary)		Group Means H1			Standard Deviation of Standardized Means H0 (Equiv. Boundary)		
Power	Total N	Group ni	Means μ0	SD of μ0 σm0	Means μ1	SD of μ1 σm1	Standard Deviation σ	f0	H1 f1	Alpha
0.38245	40	10	μ0(1)	1	μ1(1)	0.5	2	0.5	0.25	0.05
0.65712	80	20	μ0(1)	1	μ1(1)	0.5	2	0.5	0.25	0.05
0.81888	120	30	μ0(1)	1	μ1(1)	0.5	2	0.5	0.25	0.05
0.90803	160	40	μ0(1)	1	μ1(1)	0.5	2	0.5	0.25	0.05
0.95474	200	50	μ0(1)	1	μ1(1)	0.5	2	0.5	0.25	0.05
0.97828	240	60	μ0(1)	1	μ1(1)	0.5	2	0.5	0.25	0.05
0.98979	280	70	μ0(1)	1	μ1(1)	0.5	2	0.5	0.25	0.05

Item	Values
μ0(1)	5, 5, 7, 7
μ1(1)	5, 5, 6, 6

Power The probability of rejecting a false null hypothesis of non-equivalence in favor of the alternative hypothesis of equivalence.
N The total number of subjects in the study.
ni The Sample Size per Group is the number of items sampled from each group in the study.
μ0 The Group Means | H0 is the set name and number of the group means under the null hypothesis. These values are used to form the equivalence boundary, f0.
σm0 The Standard Deviation of Group Means (μ0) | H0 is the standard deviation of the equivalence means. Note that this value also depends on the group sample sizes.
μ1 The Group Means | H1 is the set name and number of the group means under the alternative hypothesis. This is the set of means at which the power is calculated.
σm1 The Standard Deviation of Group Means (μ1) | H1 is the standard deviation of the group means assumed by the alternative hypothesis. Note that this value also depends on the group sample sizes.
σ The common standard deviation of the responses within a group.
f0 The Standard Deviation of Standardized Means | H0 is the standard deviation of the standardized means assumed by the null hypothesis, H0. This is the upper bound of equivalence. Note that you must have f1 < f0.
f1 The Standard Deviation of Standardized Means | H1 is the standard deviation of the standardized means assumed by the alternative hypothesis, H1. Note that you must have f1 < f0.
Alpha The significance level of the test: the probability of rejecting the null hypothesis of non-equivalent means when it is actually true.

Group Sample Size Details

n	N	Group Sample Sizes	Group Allocation Proportions
n(1)	40	10, 10, 10, 10	0.25, 0.25, 0.25, 0.25
n(2)	80	20, 20, 20, 20	0.25, 0.25, 0.25, 0.25
n(3)	120	30, 30, 30, 30	0.25, 0.25, 0.25, 0.25
n(4)	160	40, 40, 40, 40	0.25, 0.25, 0.25, 0.25
n(5)	200	50, 50, 50, 50	0.25, 0.25, 0.25, 0.25
n(6)	240	60, 60, 60, 60	0.25, 0.25, 0.25, 0.25
n(7)	280	70, 70, 70, 70	0.25, 0.25, 0.25, 0.25

Summary Statements

A one-way ANOVA design with 4 groups will be used to test whether the 4 group means are equivalent. The equivalence comparison will be made using an F-test with a Type I error rate (α) of 0.05. Defining the equivalence boundary, the group means under the null hypothesis are 5, 5, 7, 7, and the standard deviation of the equivalence boundary means is 1 (standard deviation of the standardized means under the null hypothesis = 0.5). The common within-group standard deviation of responses for all groups is assumed to be 2. To detect the means 5, 5, 6, 6 (standard deviation of group means to detect = 0.5, standard deviation of the standardized group means under the alternative hypothesis = 0.25), with group sample sizes of 10, 10, 10, 10 (for a total of 40 subjects), the power is 0.38245.

Dropout-Inflated Sample Size

Dropout Rate	Sample Size N	Dropout-Inflated Enrollment Sample Size N'	Expected Number of Dropouts D
20%	40	50	10
20%	80	100	20
20%	120	150	30
20%	160	200	40
20%	200	250	50
20%	240	300	60
20%	280	350	70

Dropout Rate The percentage of subjects (or items) that are expected to be lost at random during the course of the study and for whom no response data will be collected (i.e., will be treated as "missing"). Abbreviated as DR.
N The evaluable sample size at which power is computed (as entered by the user). If N subjects are evaluated out of the N' subjects that are enrolled in the study, the design will achieve the stated power.
N' The total number of subjects that should be enrolled in the study in order to obtain N evaluable subjects, based on the assumed dropout rate. N' is calculated by inflating N using the formula N' = N / (1 - DR), with N' always rounded up. (See Julious, S.A. (2010) pages 52-53, or Chow, S.C., Shao, J., Wang, H., and Lokhnygina, Y. (2018) pages 32-33.)
D The expected number of dropouts. D = N' - N.

Dropout Summary Statements

Anticipating a 20% dropout rate, 50 subjects should be enrolled to obtain a final sample size of 40 subjects.

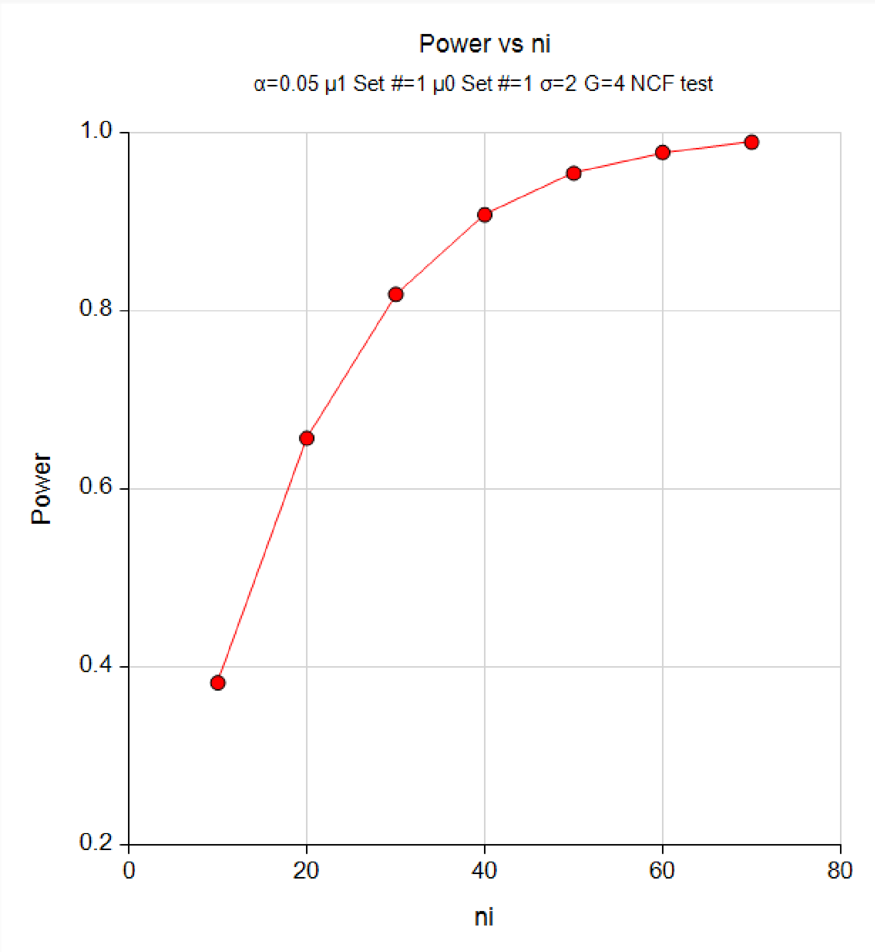
References

Jan, S-L and Shieh, G. 2019. 'On the Extended Welch Test for Assessing Equivalence of Standardized Means'. Statistics in Biopharmaceutical Research. DOI:10.1080/19466315.2019.1654915
Shieh, G. 2016. 'A comparative appraisal of two equivalence tests for multiple standardized effects'. Computer Methods and Programs in Biomedicine, Vol 126, Pages 110-117. http://dx.doi.org/10.1016/j.cmpb.2015.12.004
Wellek, Stefan. 2010. Testing Statistical Hypotheses of Equivalence and Noninferiority, 2nd Edition. CRC Press. New York.

This report shows the numeric results of this power study.

Plots Section

Plots



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

Example 2 – Finding the Sample Size Necessary to Reject

Continuing with the last example, we will determine how large the sample size would need to have been for alpha = 0.05 and power = 0.80 or 0.9.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 2** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab

Solve For	**Sample Size**
Power	**0.8 0.9**
Alpha	**0.05**
G (Number of Groups)	**4**
Group Allocation Input Type	**Equal (n1 = ··· = nG)**
μ0 Input Type	**Enter μ0 (Group Means|H0)**
μ0 (Group Means|H0)	**5 5 7 7**
μ1 Input Type	**Enter μ1 (Group Means|H1)**
μ1 (Group Means|H1)	**5 5 6 6**
σ (Standard Deviation)	**2**

Output

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

Numeric Results

Solve For: Sample Size
Number of Groups: 4

	Sample Size		Group Means					Standard Deviation of Standardized Means		
			H0 (Equiv. Boundary)		H1					
Power	Total N	Group ni	Means μ0	SD of μ0 σm0	Means μ1	SD of μ1 σm1	Standard Deviation σ	H0 (Equiv. Boundary) f0	H1 f1	Alpha
0.80657	116	29	μ0(1)	1	μ1(1)	0.5	2	0.5	0.25	0.05
0.90143	156	39	μ0(1)	1	μ1(1)	0.5	2	0.5	0.25	0.05

Item	Values
μ0(1)	5, 5, 7, 7
μ1(1)	5, 5, 6, 6

Group Sample Size Details

n	N	Group Sample Sizes	Group Allocation Proportions
n(1)	116	29, 29, 29, 29	0.25, 0.25, 0.25, 0.25
n(2)	156	39, 39, 39, 39	0.25, 0.25, 0.25, 0.25

The required sample size jumps from 116 to 156 as the power is increased.

Example 3 – Validation using Shieh (2016)

Shieh (2016) page 114 presents an example in which alpha = 0.05, G = 3, σ = 1, σm1 = 0.05, and σm0 = 0.25, and power = 0.6503. The resulting sample size is 48 per group for a total of 144.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 3** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab

Solve For .... **Sample Size**
Power... **0.6503**
Alpha.. **0.05**
G (Number of Groups) **3**
Group Allocation Input Type .... **Equal (n1 = ⋯ = nG)**
μ0 Input Type.. **Enter σm0 (SD of μ0)**
σm0 (SD of μ0) **0.25**
μ1 Input Type.. **Enter σm1 (SD of μ1)**
σm1 (SD of μ1) **0.05**
σ (Standard Deviation).................................. **1**

Output

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

Numeric Results

Solve For: Sample Size
Number of Groups: 3

	Sample Size		Group Means			Standard Deviation of Standardized Means		
Power	Total N	Group ni	H0 (Equiv. Boundary) SD of μ0 σm0	H1 SD of μ1 σm1	Standard Deviation σ	H0 (Equiv. Boundary) f0	H1 f1	Alpha
0.6503	144	48	0.25	0.05	1	0.25	0.05	0.05

Group Sample Size Details

n	N	Group Sample Sizes	Group Allocation Proportions
n(1)	144	48, 48, 48	0.333, 0.333, 0.333

PASS also found N = 144. The procedure is validated.

Example 4 – Comparison with Two-Sample Equivalence Test

It is interesting to compare the results from this procedure with G = 2 with results from the *Two-Sample T-Tests for Equivalence Assuming Equal Variance* procedure. Here is a copy of an analysis run for that procedure.

Numeric Results

Solve For: Sample Size
Difference: δ = μ1 - μ2 = μT - μR
Hypotheses: H0: δ ≤ EL or δ ≥ EU vs. H1: EL < δ < EU
Test Type: Two One-Sided Equal-Variance T-Tests

Power		Sample Size			Equivalence Limits		Actual	Standard	
Target	Actual	N1	N2	N	Lower EL	Upper EU	Difference δ	Deviation σ	Alpha
0.9	0.90009	2707	2707	5414	-10	10	2	100	0.05

To duplicate this example, we set alpha = 0.05, G = 2, power = 0.9, σ = 100, $\mu_1 = 0$, $\mu_2 = 2$, $E_1 = 0$, and $E_2 = 10$. The sample size will be calculated.

Note that we set the difference of the two means to match the value of δ and the difference between the equivalence means to be one-half the difference between the two equivalence bounds.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 4** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab

Solve For .... **Sample Size**
Power.. **0.9**
Alpha.. **0.05**
G (Number of Groups) **2**
Group Allocation Input Type .... **Equal (n1 = ⋯ = nG)**
μ0 Input Type.. **Enter μ0 (Group Means|H0)**
μ0 (Group Means|H0) **0 10**
μ1 Input Type.. **Enter μ1 (Group Means|H1)**
μ1 (Group Means|H1) **0 2**
σ (Standard Deviation).................................. **100**

Output

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

Numeric Results

Solve For: Sample Size
Number of Groups: 2

	Sample Size		Group Means					Standard Deviation of Standardized Means		
			H0 (Equiv. Boundary)		H1					
Power	Total N	Group ni	Means μ0	SD of μ0 σm0	Means μ1	SD of μ1 σm1	Standard Deviation σ	H0 (Equiv. Boundary) f0	H1 f1	Alpha
0.9	5414	2707	μ0(1)	5	μ1(1)	1	100	0.05	0.01	0.05

Item	Values
μ0(1)	0, 10
μ1(1)	0, 2

Group Sample Size Details

n	N	Group Sample Sizes	Group Allocation Proportions
n(1)	5414	2707, 2707	0.5, 0.5

PASS also found N = 5414. So, the two procedures are in perfect agreement.