Chapter 270

Cluster Randomization – Create Cluster Means Dataset

Introduction

A *cluster randomization trial* occurs when whole groups or *clusters* of individuals are treated together. Examples of such clusters are clinics, hospitals, cities, schools, or neighborhoods. In the two-group case, each cluster is randomized to receive a particular treatment. That is, all individuals in a cluster receive the same treatment. One way to analyze the data from such a design is to form the means of each cluster and then analyze those means using a two-sample t-test, an unequal-variance two-sample t-test, or a regression analysis.

This procedure creates a new dataset containing the cluster means from an original dataset containing information on individuals. This summarized dataset can then be analyzed further using t-tests or regression analysis.

Cluster-randomized trials are covered in several texts, including Hayes and Moulton (2017), Campbell and Walters (2014), Eldridge and Kerry (2012), Donner and Klar (2000), and Murray (1998).

Data Structure

A dataset analyzed by this procedure requires three variables: a categorical cluster variable, a categorical group variable, and a numeric data variable.

Here is an example of a dataset that can be successfully manipulated with this procedure. The Cluster column gives the cluster identification number. The Group column gives an identification number of the group to which each cluster belongs. All group values in a given cluster should be equal. A Data column (Pulse) gives the endpoint value for each individual. This example dataset is called **ClusRandMeans**.

ClusRandMeans dataset (subset)

Cluster	Group	Pulse
1	1	60
1	1	56
1	1	58
1	1	58
1	1	64
1	1	54
1	1	51
1	1	57
1	1	47
1	1	58
1	1	62
1	1	50
1	1	65
.	.	.
.	.	.
.	.	.

Procedure Options

This section describes the options available in this procedure.

Variables Tab

The options on this screen control the variables that are used in the analysis.

Cluster Variables

Cluster Variable(s)

The cluster variable defines how the data will be summarized. Each category in this variable will result in a separate row of the new, summarized database.

Usually, you will specify one Cluster variable and one Treatment Group variable, but you can specify up to a total of seven cluster variables and one treatment group variable.

The categories in these variables may be text (e.g. “Low, Med, High”) or numeric (e.g. “1, 2, 3”).

Statistics are computed for each combination of values from all variables entered here.

Category Order

The data values in each variable will be sorted alpha-numerically before being listed. If you want the values to be displayed in a different order, specify a custom value order for the data columns entered here using the Column Info Table on the Data Window.

Treatment Group Variable

The treatment group variable defines the treatment group associated with each cluster. The program assumes that all rows in a particular cluster have the same treatment group. The function of this variable is to define the treatment groups on the summarized dataset.

Only one Treatment Group Variable may be specified. The categories in this variable may be text (e.g. “Low, Med, High”) or numeric (e.g. “1, 2, 3”).

Numeric Variables to be Summarized for each Cluster

Primary Endpoint Variable(s)

The primary endpoint is sometimes called the response or dependent variable.

Specify one or more variables whose counts, means, standard deviations, and sums are to be calculated for each cluster.

The data in these variables must be numeric. Text values will be skipped in the calculations.

Covariate Variable(s)

Covariates are additional variables that may be useful, so their values are summarized on the summary dataset.

Specify one or more variables whose descriptive statistics (counts, means, standard deviations, and sums) are to be calculated for each cluster.

The data in these variables must be numeric. Text values will be skipped.

Frequency (Count) Variable

Frequency Variable

Specify an optional frequency (count) variable. This data column contains integers that represent the number of observations (frequency) associated with each row of the dataset.

When Omitted

If this option is left blank, each dataset row has a frequency of one. This variable lets you modify that frequency. This may be useful when your data are tabulated and you want to enter counts.

Cluster Statistical Summary Storage

Store the Cluster Summaries in a New NCSS Data File…

When this box is checked, the current dataset will close and the resulting cluster summaries will be written to a new data table.

You will be prompted to save any changes to the current dataset before continuing. Any unsaved data will be lost!

Output File

The new data table with the cluster summaries will automatically be saved in the output file entered below. If no output file is specified, no file will be saved. You can manually save the output data file to any file you wish.

Output File Name

Enter an output file name in which to store the data. Double-click the box or click on the file selection button to browse for a file or folder.

The selected output file will be overwritten and the current database will be closed, so make sure to save all data before continuing.

No Output File Name

If no output file is specified, the summary output data will not be automatically saved. You can manually save the output data file to any file you wish. If you have chosen to reopen the current dataset without entering an output file name, then the summary output data will be lost.

Cluster Statistics Storage

Select how the cluster statistics will be stored in the output file. This option does not affect calculations.

The options are

- **Store as Rows**
  Data variable names and associated summary statistics are stored row-by-row in the output data table.

Variable	Group	Count	Mean
Var 1	A	12	15.7
Var 1	B	37	12.6
Var 2	A	12	27.5
Var 2	B	37	33.6

- **Store as Columns (Recommended)**
  Data variable names and associated summary statistics are stored column-by-column in the output data table.

Group	Var 1 Count	Var 1 Mean	Var 2 Count	Var 2 Mean
A	12	15.7	12	27.5
B	37	12.6	37	33.6

In both cases, the summary statistics for the cluster variables are listed row-by-row.

Automatically Reopen the Current Dataset…

The storage operation requires the current dataset to close while the summary data is written to the new data table. When this box is checked, the current dataset will automatically reopen once the process is complete.

No Output File Name

If no output file is specified, the summary output data will not be automatically saved. If you have chosen to reopen the current dataset without entering an output file name, then the summary output data will be lost.

Unsaved Data Warning

If you have not saved the current dataset to a file, the data will not reopen and will be lost!

Missing Values Tab

This panel lets you specify up to five missing values (besides the default of blank). For example, ‘0’, ‘9’, or ‘NA’ may be missing values in your database.

Missing Value Inclusion

Specifies whether to include observations with missing values in the tables.

Delete All indicates that you want the missing values totally ignored.

Include in All indicates that you want the missing values treated just like any other category.

Missing Values

Specify up to five individual missing values here, one per box.

Reports Options Tab

The options on this screen control the appearance of the reports.

Report Options

Variable Names

This option lets you select whether to display only variable names, variable labels, or both.

Value Labels

Value Labels are used to make reports more legible by assigning meaningful labels to numbers and codes.

Data Values

All data are displayed in their original format, regardless of whether a value label has been set or not.

Value Labels

All values of variables that have a value label variable designated are converted to their corresponding value label when they are output. This does not modify their value during computation.

Both

Both data value and value label are displayed.

Summary Table Formatting

Column Justification

Specify whether data columns in the tables will be left or right justified.

Column Widths

Specify how the widths of columns in the contingency tables will be determined.

The options are

- **Autosize to Minimum Widths**
  Each data column is individually resized to the smallest width required to display the data in the column. This usually results in columns with different widths. This option produces the most compact table possible, displaying the most data per page.
- **Autosize to Equal Minimum Width**
  The smallest width of each data column is calculated and then all columns are resized to the width of the widest column. This results in the most compact table possible where all data columns have the same with. This is the default setting.
- **Custom (User-Specified)**
  Specify the widths (in inches) of the columns directly instead of having the software calculate them for you.

Custom Widths

Enter one or more values for the widths (in inches) of columns in the contingency tables.

- **Single Value**
  If you enter a single value, that value will be used as the width for all data columns in the table.

- **List of Values**

  Enter a list of values separated by spaces corresponding to the widths of each column. The first value is used for the width of the first data column, the second for the width of the second data column, and so forth. Extra values will be ignored. If you enter fewer values than the number of columns, the last value in your list will be used for the remaining columns.

  Type the word "Autosize" for any column to cause the program to calculate it's width for you. For example, enter "1 Autosize 0.7" to make column 1 be 1 inch wide, column 2 be sized by the program, and column 3 be 0.7 inches wide.

Wrap Column Headings onto Two Lines

Check this option to make column headings wrap onto two lines. Use this option to condense your table when your data are spaced too far apart because of long column headings.

Use Short Statistical Names on Reports and Plots

Normally, the names of the statistical items in the reports and plots are complete names, such as "Standard Deviation." Checking this option causes a shorter name, such as "SD", to be used instead so that more columns can be displayed together in tables and so that plot titles and labels are not so long. A maximum of 13 columns can be displayed on a single row.

Decimal Places

Item Decimal Places

These decimal options allow the user to specify the number of decimal places for items in the output. Your choice here will not affect calculations; it will only affect the format of the output.

- **Auto**

  If one of the "Auto" options is selected, the ending zero digits are not shown. For example, if "Auto (0 to 7)" is chosen,

  0.0500 is displayed as 0.05
  1.314583689 is displayed as 1.314584

  The output formatting system is not designed to accommodate "Auto (0 to 13)", and if chosen, this will likely lead to lines that run on to a second line. This option is included, however, for the rare case when a very large number of decimals is needed.

Plots Tab

The options on this panel control the appearance of the plots that are displayed. Click the plot format button to change the plot settings.

Show Statistic Plots

Check to display a separate plot for each statistic in each table. This may result in several plots being created for each table. Plots are created with a table's row item on the group axis. If there is only one row in a table, then no plot is output.

Example 1 – Creating a Summarized Dataset from the ClusRandMeans Data

This section presents an example of how to summarize the data contained in the ClusRandMeans dataset.

You may follow along here by making the appropriate entries or load the completed template **Example 1** by clicking on Open Example Template from the File menu of this procedure window.

1 Open the ClusRandMeans dataset.

- From the File menu of the NCSS Data window, select **Open Example Data**.
- Click on the file **ClusRandMeans.NCSS**.
- Click **Open**.

2 Open the Cluster Randomization – Create Cluster Means Dataset window.

- Using the Analysis menu, the Tools Menu, or the Procedure Navigator, find and select the **Cluster Randomization – Create Cluster Means Dataset** procedure.
- On the menus, select **File**, then **New Template**. This will fill the procedure with the default template.

3 Select the variables.

- Select the **Variables tab**.
- Set the **Cluster Variable(s)** to **Cluster**.
- Set the **Treatment Group Variable** to **Group**.
- Set the **Primary Endpoint Variable(s)** to **Pulse**.
- Check the **Store the Cluster Summaries to a New NCSS Data File box**.
- Set **Output File Name** to **%mydocs_NCSS%\Data\Cluster Means.NCSS**.
- Set **Cluster Statistics Storage** to **Store as Column**.
- Check **Automatically Reopen the Current Dataset after the Save Operation Completes**.

4 Run the procedure.

- From the Run menu, select **Run Procedure**. Alternatively, just click the green Run button.

Summary List Storage Information

Output Data File Name:	{NCSS Documents Folder}\Cluster Means.NCSS
Original Raw Data File:	{Example Data Folder}\ClusRandMeans.NCSS
Data Variable(s):	(1) Pulse
Group Variable(s):	(2) Cluster, Group
Summary Statistic(s):	(4) Count, Mean, SD, Sum

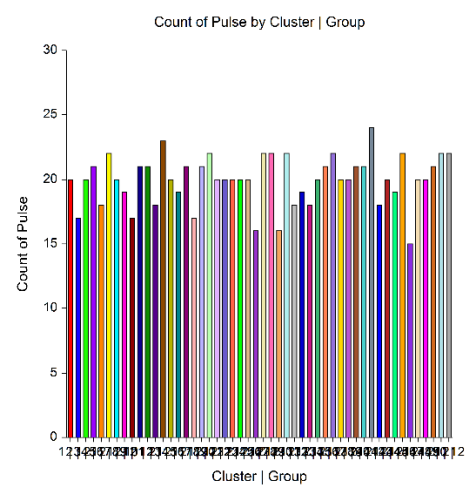
This report shows where the new, summarized file is stored.

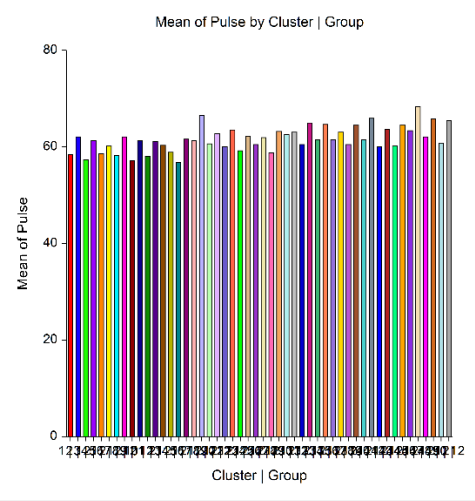
Summary List of Pulse

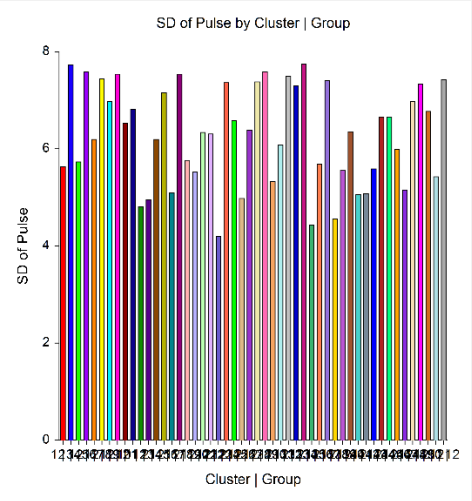
Cluster | Group	Statistics for Pulse			
	Count	Mean	SD	Sum
1 | 1	20	58.45	5.633313	1169
2 | 2	17	62.11765	7.72077	1056
3 | 1	20	57.3	5.731721	1146
4 | 2	21	61.28571	7.590407	1287
5 | 1	18	58.5	6.195349	1053
6 | 2	22	60.22727	7.444601	1325
7 | 1	20	58.25	6.972691	1165
8 | 2	19	62.15789	7.537043	1181
.	.	.	.	.
.	.	.	.	.
.	.	.	.	.

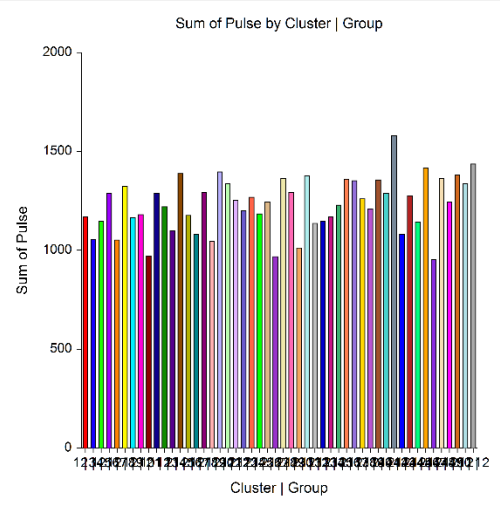
This report displays count, mean, standard deviation, and sum of the Pulse variable for each cluster.

Plots of each Statistic for Pulse









This report displays the statistics cluster by cluster. Of particular interest are the means and whether the standard deviations (SD's) can be assumed to be equal.

New Cluster Means Dataset

You can open the new Cluster Means dataset by using the File menu on the Data Window. The following dataset will appear.

Cluster	Group	Pulse_Count	Pulse_Mean	Pulse_SD	Pulse_Sum
1	1	20	58.45	5.63331257133099	1169
2	2	17	62.1176470588235	7.72077030597641	1056
3	1	20	57.3	5.73172151966121	1146
4	2	21	61.2857142857143	7.59040748012159	1287
5	1	18	58.5	6.19534929936775	1053
6	2	22	60.2272727272727	7.44460058848545	1325
7	1	20	58.25	6.97269109115208	1165
8	2	19	62.1578947368421	7.53704302388275	1181
9	1	17	57.1764705882353	6.52145779444335	972
10	2	21	61.3333333333333	6.82153452921946	1288
11	1	21	58.0952380952381	4.80525505987728	1220
12	2	18	61.1666666666667	4.9378490196822	1101
13	1	23	60.2608695652174	6.19543373860831	1386
14	2	20	58.85	7.15449803307424	1177
15	1	19	56.8421052631579	5.08006078151233	1080
16	2	21	61.5238095238095	7.5406833086866	1292
17	1	17	61.2941176470588	5.76373040966474	1042
18	2	21	66.5238095238095	5.51923045015379	1397
19	1	22	60.6818181818182	6.34249735729332	1335
20	2	20	62.65	6.31018391591177	1253
21	1	20	60.05	4.18612998012798	1201
22	2	20	63.5	7.36635309327057	1270
23	1	20	59.25	6.56846533385884	1185
24	2	20	62.3	4.97467269486673	1246
25	1	16	60.5	6.37704215656966	968
26	2	22	61.9545454545455	7.37096797111267	1363
27	1	22	58.7272727272727	7.57930652803325	1292
28	2	16	63.25	5.32290647422377	1012
29	1	22	62.5	6.07688830147234	1375
30	2	18	63.0555555555556	7.48702581507207	1135
31	1	19	60.4210526315789	7.29014395128171	1148
32	2	18	64.9444444444444	7.74195766565098	1169
33	1	20	61.4	4.42956573848712	1228
34	2	21	64.7142857142857	5.67576300723398	1359
35	1	22	61.5	7.41138120923296	1353
36	2	20	63.1	4.55261636748295	1262
37	1	20	60.45	5.54858919954101	1209
38	2	21	64.4761904761905	6.35310197949826	1354
39	1	21	61.3809523809524	5.05446525832546	1289
40	2	24	65.875	5.0760520434513	1581
41	1	18	60	5.58358940003966	1080
42	2	20	63.75	6.64811013905851	1275
43	1	19	60.1578947368421	6.66052348538876	1143
44	2	22	64.4090909090909	5.9893484096598	1417
45	1	15	63.4	5.15197604253525	951
46	2	20	68.25	6.98023525466917	1365
47	1	20	62.15	7.32174123667602	1243
48	2	21	65.7142857142857	6.76862509777914	1380
49	1	22	60.7272727272727	5.41762395803265	1336
50	2	22	65.3636363636364	7.41649034276517	1438

This dataset can now be analyzed using the Two-Sample T-Test procedure in which the two groups are defined by the Group column and the Response is the Pulse_Mean column. We suggest that the Randomization test, the Mann-Whitney U test, and/or the Aspin-Welch Unequal-Variance T-Test be used to test for significance.

Example 1a – Analyzing the Summarized Dataset

This section continues the analysis begun with Example 1 by analyzing the summarized dataset, **Cluster Means**, using the Two-Sample T-Test procedure.

You may follow along here by making the appropriate entries or load the completed template **Example 1a** by clicking on Open Example Template from the File menu of the Two-Sample T-Test procedure window.

1 Open the Cluster Means dataset that you just created in Example 1.

- From the File menu of the NCSS Data window, select **Cluster Means** in the list of recent datasets.

or

- From the File menu of the NCSS Data window, select **Open Example Data**.
- Click on the file **Cluster Means.NCSS**.
- Click **Open**.

2 Open the Two-Sample T-Test window.

- Using the Analysis menu or the Procedure Navigator, find and select the **Two-Sample T-Test** procedure.
- On the menus, select **File**, then **New Template**. This will fill the procedure with the default template.

3 Select the variables.

- Select the **Variables tab**.
- Set the **Data Input Type** to **Response Variable(s) and Group Variable(s)**.
- Set the **Response Variable(s)** to **Pulse_Mean**.
- Set the **Group Variables** to **Group**.

4 Select the reports.

- Select the **Reports tab**.
- Check the **Descriptive Statistics and Confidence Intervals** report.
- Check the **Confidence Interval of μ1 – μ2** report.
- Check the **Equal-Variance T-Test** report.
- Check the **Unequal-Variance T-Test** report.
- Check the **Randomization Test** report.
- Check the **Mann-Whitney U Test** report.
- Check the **Exact Test** report.
- Check the **Normal Approximation Test** report.
- Check the **Normal Approximation Test with Continuity Correction** report.
- Check the **Tests of Assumptions** report.

5 Select the plots.

- Select the **Plots tab**.
- Check the **Probability Plot** and **Box Plot** report.

6 Run the procedure.

- From the Run menu, select **Run Procedure**. Alternatively, just click the green Run button.

Two-Sample T-Test Report

Descriptive Statistics

Variable	Count	Mean	Standard Deviation of Data	Standard Error of Mean	T*	95% LCL of Mean	95% UCL of Mean
Group=1	25	59.9786	1.716245	0.3432491	2.0639	59.27017	60.68703
Group=2	25	63.29973	2.141713	0.4283426	2.0639	62.41567	64.18378

Descriptive Statistics for the Median

Variable	Count	Median	95% LCL of Median	95% UCL of Median
Group=1	25	60.26087	58.72727	60.72727
Group=2	25	63.1	62.11765	64.47619

Two-Sided Confidence Interval for μ1 - μ2

Variance Assumption	DF	Mean Difference	Standard Deviation	Standard Error	T*	95% C. I. of μ1 - μ2 Lower Limit	95% C. I. of μ1 - μ2 Upper Limit
Equal	48	-3.321125	1.940674	0.5489056	2.0106	-4.424773	-2.217476
Unequal	45.82	-3.321125	2.744528	0.5489056	2.0131	-4.426129	-2.21612

Equal-Variance T-Test

Alternative Hypothesis	Mean Difference	Standard Error	T-Statistic	DF	Prob Level	Reject H0 at α = 0.050?
μ1 - μ2 ≠ 0	-3.321125	0.5489056	-6.0504	48	0.00000	Yes

Aspin-Welch Unequal-Variance T-Test (This is a key report)

Alternative Hypothesis	Mean Difference	Standard Error	T-Statistic	DF	Prob Level	Reject H0 at α = 0.050?
μ1 - μ2 ≠ 0	-3.321125	0.5489056	-6.0504	45.82	0.00000	Yes

Randomization Tests

Alternative Hypothesis: |μ1 - μ2| ≠ 0. This is a Two-Sided Test.
Number of Monte Carlo samples: 10000

Variance Assumption	Prob Level	Reject H0 at α = 0.050?
Equal Variance	0.00010	Yes
Unequal Variance	0.00010	Yes

Mann-Whitney U or Wilcoxon Rank-Sum Test for Difference in Location (This is another key report)

Variable	Mann-Whitney U	Sum of Ranks (W)	Mean of W	Std Dev of W
Group=1	67	392	637.5	51.53882
Group=2	558	883	637.5	51.53882

Number of Sets of Ties = 0, Multiplicity Factor = 0

Test Type	Alternative Hypothesis	Z-Value	Prob Level	Reject H0 at α = 0.050?
Exact*	Location Diff. ≠ 0			Yes
Normal Approximation	Location Diff. ≠ 0	-4.7634	0.00000	Yes
Normal Approx. with C.C.	Location Diff. ≠ 0	-4.7537	0.00000	Yes

* The Exact Test is provided only when there are no ties and the sample size is ≤ 20 in both groups.

Cluster Randomization – Create Cluster Means Dataset

Tests of the Normality Assumption for Group=1

Normality Test	Test Statistic	Prob Level	Reject H0 of Normality at α = 0.050?
Shapiro-Wilk	0.9708	0.66618	No
Skewness	-0.2911	0.77097	No
Kurtosis	-0.5891	0.55582	No
Omnibus (Skewness or Kurtosis)	0.4317	0.80584	No

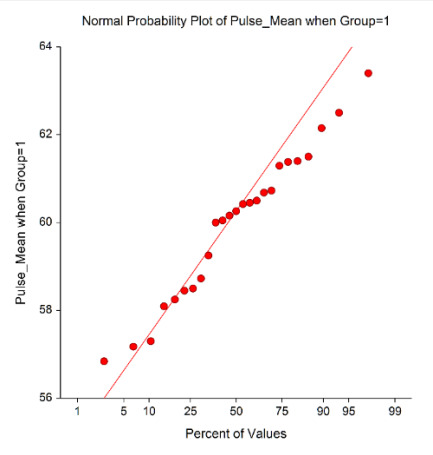
Tests of the Normality Assumption for Group=2

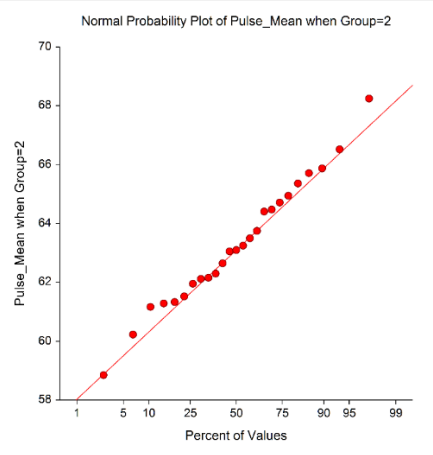
Normality Test	Test Statistic	Prob Level	Reject H0 of Normality at α = 0.050?
Shapiro-Wilk	0.9898	0.99490	No
Skewness	0.5264	0.59860	No
Kurtosis	0.3194	0.74941	No
Omnibus (Skewness or Kurtosis)	0.3791	0.82732	No

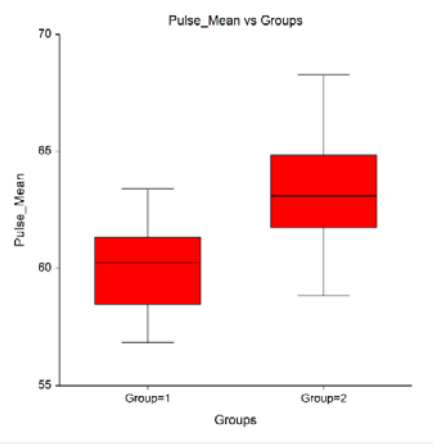
Tests of the Equal Variance Assumption

Equal-Variance Test	Test Statistic	Prob Level	Reject H0 of Equal Variances at α = 0.050?
Variance-Ratio	1.5573	0.28488	No
Modified-Levene	1.0372	0.31357	No

Plots Section







This report displays the results of the various tests. The probability plots let you assess the validity of the normality assumptions. The box plots show the separation between the groups.