## Chapter 426

# Two-Sample Z-Tests Assuming Equal Variance

## Introduction

This procedure provides sample size and power calculations for one- or two-sided two-sample z-tests when the variances of the two groups (populations) are assumed to be known and equal. The assumed difference between means can be specified by entering the means for the two groups and letting the software calculate the difference or by entering the difference directly.

The design corresponding to this test procedure is sometimes referred to as a *parallel-groups* design. This design is used in situations such as the comparison of the income level of two regions, the nitrogen content of two lakes, or the effectiveness of two drugs.

There are several statistical tests available for the comparison of the center of two populations. This procedure is specific to the two-sample z-test assuming known and equal variance. You can examine the sections below to identify whether the assumptions and test statistic you intend to use in your study match those of this procedure, or if one of the other **PASS** procedures may be more suited to your situation.

# Other PASS Procedures for Comparing Two Means or Medians

Procedures in **PASS** are primarily built upon the testing methods, test statistic, and test assumptions that will be used when the analysis of the data is performed. You should check to identify that the test procedure described below in the Test Procedure section matches your intended procedure. If your assumptions or testing method are different, you may wish to use one of the other two-sample procedures available in **PASS**. These procedures are Two-Sample T-Tests Allowing Unequal Variance, Two-Sample T-Tests Assuming Equal Variance, Two-Sample Z-Tests Allowing Unequal Variance, and the nonparametric Mann-Whitney-Wilcoxon (also known as the Mann-Whitney U or Wilcoxon rank-sum test) procedure. The methods, statistics, and assumptions for those procedures are described in the associated chapters.

If you wish to show that the mean of one population is larger (or smaller) than the mean of another population by a specified amount, you should use one of the clinical superiority procedures for comparing means. Non-inferiority, equivalence, and confidence interval procedures are also available.

## **Test Assumptions**

When running a two-sample equal-variance z-test, the basic assumptions are that the distributions of the two populations are normal, and that the variances of the two distributions are known and are the same. If those assumptions are not likely to be met, another testing procedure could be used, and the corresponding procedure in **PASS** should be used for sample size or power calculations.

## **Test Procedure**

If we assume that  $\mu_1$  and  $\mu_2$  represent the means of the two populations of interest, and that  $\delta=\mu_1-\mu_2$ , the null hypothesis for comparing the two means is  $H_0$ :  $\mu_1=\mu_2$  (or  $H_0$ :  $\delta=0$ ). The alternative hypothesis can be any one of

Two-Sided:  $H_1: \mu_1 \neq \mu_2 \quad (\text{or } H_1: \delta \neq 0)$ Upper One-Sided:  $H_1: \mu_1 > \mu_2 \quad (\text{or } H_1: \delta > 0)$ Lower One-Sided:  $H_1: \mu_1 < \mu_2 \quad (\text{or } H_1: \delta < 0)$ 

depending upon the desire of the researcher or the protocol instructions. A suitable Type I error probability ( $\alpha$ ) is chosen for the test, the data is collected, and a z-statistic is generated using the formula:

$$z = \frac{\bar{x}_1 - \bar{x}_2}{\sigma \sqrt{\frac{1}{n_1} + \frac{1}{n_2}}}$$

The null hypothesis is rejected in favor of the alternative if,

for  $H_1: \mu_1 \neq \mu_2$  (or  $H_1: \delta \neq 0$ ),

$$z < z_{\alpha/2}$$
 or  $z > z_{1-\alpha/2}$ ,

for  $H_1: \mu_1 > \mu_2$  (or  $H_1: \delta > 0$ ),

$$z > z_{1-\alpha}$$

or, for  $H_1: \mu_1 < \mu_2$  (or  $H_1: \delta < 0$ ),

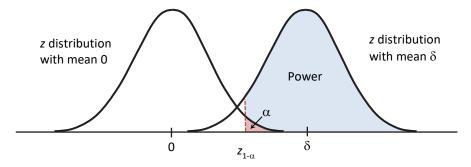
$$z < z_{\alpha}$$
.

Comparing the z-statistic to the cut-off z-value (as shown here) is equivalent to comparing the p-value to  $\alpha$ .

## **Power Calculation**

This section describes the procedure for computing the power from  $n_1$  and  $n_2$ ,  $\alpha$ , the assumed  $\mu_1$  and  $\mu_2$ , and the known common standard deviation,  $\sigma_1 = \sigma_2 = \sigma$ . Two good references for these methods are Julious (2010) and Chow, Shao, and Wang (2008).

The figure below gives a visual representation for the calculation of power for a one-sided test.



If we call the assumed difference between the means,  $\delta = \mu_1 - \mu_2$ , the steps for calculating the power are as follows:

- 1. Find  $z_{1-\alpha}$  based on the *z* distribution.
- 2. Calculate the power as the probability that the test statistic z is greater than  $z_{1-\alpha}$  under the z distribution with mean  $\delta$ :

$$Power = \Pr(z > z_{1-\alpha}|\delta).$$

The algorithms for calculating power for the opposite direction and the two-sided hypotheses are analogous to this method.

When solving for something other than power, **PASS** uses this same power calculation formulation, but performs a search to determine that parameter.

## A Note on Specifying the Means or Difference in Means

When means are specified in this procedure, they are used to determine the assumed difference in means for power or sample size calculations. When the difference in means is specified in this procedure, it is the assumed difference in means for power or sample size calculations. It does not mean that the study will be powered to show that the mean difference is this amount, but rather that the design is powered to reject the null hypothesis of equal means if this were the true difference in means. If your purpose is to show that one mean is greater than another by a specific amount, you should use one of the clinical superiority procedures for comparing means.

# Example 1 - Finding the Sample Size

Researchers wish to compare two types of local anesthesia to determine whether there is a difference in time to loss of pain. Subjects will be randomized to treatment, the treatment will be administered, and the time to loss of pain measured. The anticipated time to loss of pain for one of the types of anesthesia is 9 minutes. The researchers would like to generate a sample size for the study with 90% power to reject the null hypothesis of equal loss-of-pain time if the true difference is between 2 and 10 minutes. How many participants are needed to achieve 90% power at significance levels of 0.01 and 0.05?

It is known that the standard deviation for each of the groups is 4.5.

It is unknown which treatment has lower time to loss of pain, so a two-sided test will be used.

### 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.

Solve For	Sample Size
Alternative Hypothesis	Two-Sided
Power	0.90
Alpha	0.01 0.05
Group Allocation	Equal (N1 = N2)
Input Type	Means
μ1	11 to 19 by 1
μ2	9
σ	4.5

### **Output**

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

#### **Numeric Reports**

#### **Numeric Results**

Solve For: Sample Size

Test Type: Two-Sample Equal-Variance Z-Test

Difference:  $\delta = \mu 1 - \mu 2$ 

Hypotheses: H0:  $\delta = 0$  vs. H1:  $\delta \neq 0$ 

_						M	ean		
Pov	ver 	S	ample Si	ze			Difference	Standard Deviation	
Target	Actual	N1	N2	N	μ1	μ2	δ	σ	Alpha
0.9	0.90078	151	151	302	11	9	2	4.5	0.01
0.9	0.90163	107	107	214	11	9	2	4.5	0.05
0.9	0.90022	67	67	134	12	9	3	4.5	0.01
0.9	0.90423	48	48	96	12	9	3	4.5	0.05
0.9	0.90298	38	38	76	13	9	4	4.5	0.01
0.9	0.90423	27	27	54	13	9	4	4.5	0.05
0.9	0.91190	25	25	50	14	9	5	4.5	0.01
0.9	0.91518	18	18	36	14	9	5	4.5	0.05
0.9	0.90515	17	17	34	15	9	6	4.5	0.01
0.9	0.90423	12	12	24	15	9	6	4.5	0.05
0.9	0.91775	13	13	26	16	9	7	4.5	0.01
0.9	0.90986	9	9	18	16	9	7	4.5	0.05
0.9	0.91915	10	10	20	17	9	8	4.5	0.01
0.9	0.91402	7	7	14	17	9	8	4.5	0.05
0.9	0.92280	8	8	16	18	9	9	4.5	0.01
0.9	0.93373	6	6	12	18	9	9	4.5	0.05
0.9	0.94313	7	7	14	19	9	10	4.5	0.01
0.9	0.93987	5	5	10	19	9	10	4.5	0.05

Target Power The desired power value (or values) entered in the procedure. Power is the probability of rejecting a false null

hypothesis.

Actual Power The power obtained in this scenario. Because N1 and N2 are discrete, this value is often (slightly) larger than

the target power.

N1 and N2 The number of items sampled from each population.

N The total sample size. N = N1 + N2.  $\mu 1$  and  $\mu 2$  The assumed population means.

The difference between population means at which power and sample size calculations are made.  $\delta = \mu 1$ 

μ2.

The assumed population standard deviation for each of the two groups.

Alpha The probability of rejecting a true null hypothesis.

#### **Summary Statements**

A parallel two-group design will be used to test whether the Group 1 mean is different from the Group 2 mean (H0:  $\mu1 - \mu2 = 0$  versus H1:  $\mu1 - \mu2 \neq 0$ ). The comparison will be made using a two-sided, two-sample, equal-variance Z-test, with a Type I error rate ( $\alpha$ ) of 0.01. The common (known) standard deviation for both groups is assumed to be 4.5. To detect a difference in means of  $\mu1 - \mu2 = 11 - 9 = 2$  with 90% power, the number of needed subjects will be 151 in Group 1 and 151 in Group 2.

#### **Dropout-Inflated Sample Size**

	s	ample Si	ze	E	pout-Infl Inrollme ample Si	nt	N	xpecte umber Dropout	of
Dropout Rate	N1	N2	N	N1'	N2'	N'	D1	D2	D
20%	151	151	302	189	189	378	38	38	76
20%	107	107	214	134	134	268	27	27	54
20%	67	67	134	84	84	168	17	17	34
20%	48	48	96	60	60	120	12	12	24
20%	38	38	76	48	48	96	10	10	20
20%	27	27	54	34	34	68	7	7	14
20%	25	25	50	32	32	64	7	7	14
20%	18	18	36	23	23	46	5	5	10
20%	17	17	34	22	22	44	5	5	10
20%	12	12	24	15	15	30	3	3	6
20%	13	13	26	17	17	34	4	4	8
20%	9	9	18	12	12	24	3	3	6
20%	10	10	20	13	13	26	3	3	6
20%	7	7	14	9	9	18	2	2	4
20%	8	8	16	10	10	20	2	2	4
20%	6	6	12	8	8	16	2	2	4
20%	7	7	14	9	9	18	2	2	4
20%	5	5	10	7	7	14	2	2	4

N1. N2. and N

and for whom no response data will be collected (i.e., will be treated as "missing"). Abbreviated as DR. The evaluable sample sizes at which power is computed. If N1 and N2 subjects are evaluated out of the

N1', N2', and N'

N1' and N2' subjects that are enrolled in the study, the design will achieve the stated power. The number of subjects that should be enrolled in the study in order to obtain N1, N2, and N evaluable subjects, based on the assumed dropout rate. After solving for N1 and N2, N1' and N2' are calculated by inflating N1 and N2 using the formulas N1' = N1 / (1 - DR) and N2' = N2 / (1 - DR), with N1' and N2' 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.)

D1, D2, and D

The expected number of dropouts. D1 = N1' - N1, D2 = N2' - N2, and D = D1 + D2.

#### **Dropout Summary Statements**

Anticipating a 20% dropout rate, 189 subjects should be enrolled in Group 1, and 189 in Group 2, to obtain final group sample sizes of 151 and 151, respectively.

#### References

Julious, S. A. 2010. Sample Sizes for Clinical Trials. Chapman & Hall/CRC. Boca Raton, FL.

Chow, S. C., Shao, J., and Wang, H. 2008. Sample Size Calculations in Clinical Research (Second Edition). Chapman & Hall/CRC. Boca Raton, FL.

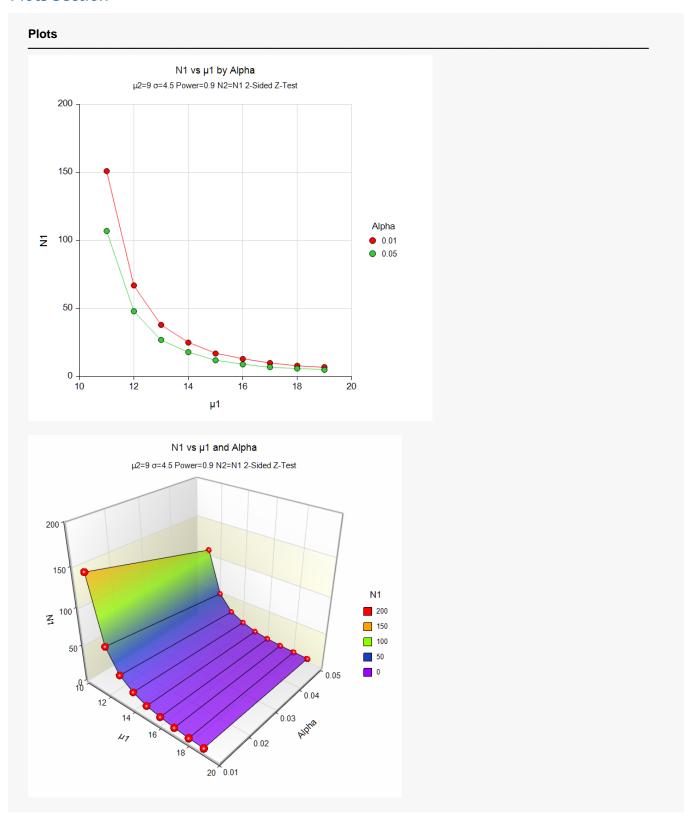
Machin, D., Campbell, M., Fayers, P., and Pinol, A. 1997. Sample Size Tables for Clinical Studies, 2nd Edition. Blackwell Science. Malden, MA.

Zar, Jerrold H. 1984. Biostatistical Analysis (Second Edition). Prentice-Hall. Englewood Cliffs, New Jersey.

These reports show the values of each of the parameters, one scenario per row.

#### **Plots Section**

**PASS Sample Size Software** 



These plots show the relationship between the mean for Group 2 and sample size for the two alpha levels.

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#### Two-Sample Z-Tests Assuming Equal Variance

To specify the difference directly to get the same results, change **Input Type** to **Difference** and enter **2 to 10 by 1** for  $\delta$ , leaving everything else the same. You may then make the appropriate entries as listed below, or open **Example 1b** by going to the **File** menu and choosing **Open Example Template**.

## **Output**

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

#### **Numeric Results**

Solve For: Sample Size

Test Type: Two-Sample Equal-Variance Z-Test

Difference:  $\delta = \mu 1 - \mu 2$ 

Hypotheses: H0:  $\dot{\delta} = \dot{0}$  vs. H1:  $\delta \neq 0$ 

Pov	ver	S	ample Si	ze	Mean Difference	Standard Deviation	
Target	Actual	N1	N2	N	δ	σ	Alpha
0.9	0.90078	151	151	302	2	4.5	0.01
0.9	0.90163	107	107	214	2	4.5	0.05
0.9	0.90022	67	67	134	3	4.5	0.01
0.9	0.90423	48	48	96	3	4.5	0.05
0.9	0.90298	38	38	76	4	4.5	0.01
0.9	0.90423	27	27	54	4	4.5	0.05
0.9	0.91190	25	25	50	5	4.5	0.01
0.9	0.91518	18	18	36	5	4.5	0.05
0.9	0.90515	17	17	34	6	4.5	0.01
0.9	0.90423	12	12	24	6	4.5	0.05
0.9	0.91775	13	13	26	7	4.5	0.01
0.9	0.90986	9	9	18	7	4.5	0.05
0.9	0.91915	10	10	20	8	4.5	0.01
0.9	0.91402	7	7	14	8	4.5	0.05
0.9	0.92280	8	8	16	9	4.5	0.01
0.9	0.93373	6	6	12	9	4.5	0.05
0.9	0.94313	7	7	14	10	4.5	0.01
0.9	0.93987	5	5	10	10	4.5	0.05

The results are the same as those obtained when the means are entered.

# Example 2 - Finding the Power

Suppose a new corn fertilizer is to be compared to a current fertilizer. The current fertilizer produces an average of about 74 lbs. per plot. The researchers need only show that there is difference in yield with the new fertilizer. They would like to consider the effect of the number of plots used on the power of the test if the improvement in yield is at least 10 lbs.

Researchers plan to use a one-sided two-sample z-test with alpha equal to 0.05. The known standard deviation for plot yield is 25 lbs. The plot group sizes of interest are 10 to 100 plots per group.

## 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.

Solve For	Power	
Alternative Hypothesis	One-Sided	
Alpha	0.05	
Group Allocation	Equal (N1 = N2)	
Sample Size Per Group	10 to 100 by 10	
Input Type	Means	
μ1	84	
μ2	74	
σ	25	

## **Output**

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

## **Numeric Reports**

#### **Numeric Results**

Solve For: Power

Test Type: Two-Sample Equal-Variance Z-Test

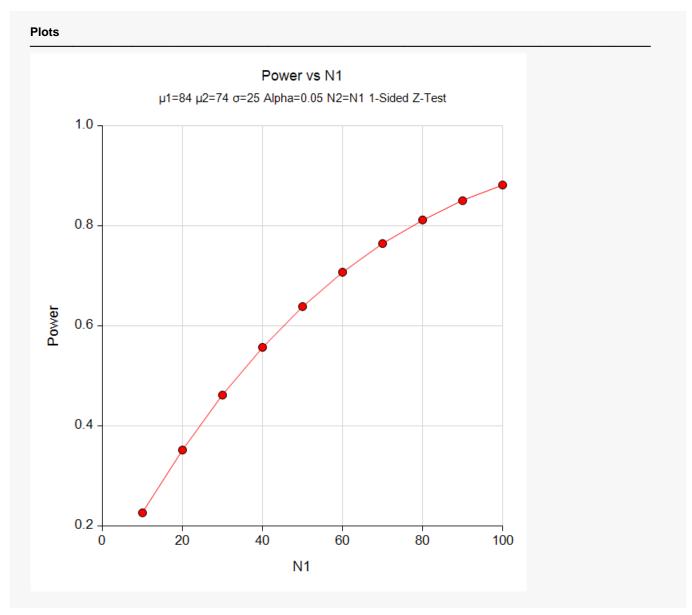
Difference:  $\delta = \mu 1 - \mu 2$ 

Hypotheses:  $H0: \dot{\delta} \leq \dot{0}$  vs.  $H1: \delta > 0$ 

	_				M	ean			
	S	ample Si	ze			Difference	Standard Deviation		
Power	N1	N2	N	μ1	μ2	δ	σ	Alpha	
0.22650	10	10	20	84	74	10	25	0.05	
0.35199	20	20	40	84	74	10	25	0.05	
0.46190	30	30	60	84	74	10	25	0.05	
0.55725	40	40	80	84	74	10	25	0.05	
0.63876	50	50	100	84	74	10	25	0.05	
0.70748	60	60	120	84	74	10	25	0.05	
0.76472	70	70	140	84	74	10	25	0.05	
0.81191	80	80	160	84	74	10	25	0.05	
0.85046	90	90	180	84	74	10	25	0.05	
0.88171	100	100	200	84	74	10	25	0.05	

These reports show the values of each of the parameters, one scenario per row.

#### **Plots Section**



This plot shows the relationship between the power and sample size.

Again, to specify the difference directly to get the same results, change **Input Type** to **Difference** and enter **10** for  $\delta$ , leaving everything else the same. You'll get the same results as those above.

# **Example 3 - Finding the Difference**

In some cases, it may be useful to determine how different the means of two populations would need to be to achieve the desired power with a specific constrained sample size.

Suppose, for example, that 80 subjects are available for a study to compare weight loss regimens. Researchers would like to determine which of the two regimens is better. The anticipated weight loss after two months is anticipated to be about 20 lbs. The researchers would like to know how different the mean weight loss must be to have a study with 90% power when alpha is 0.05 and the standard deviation is known to be 7 lbs. in both 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 3** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Solve For	Effect Size (Means or Difference)
Alternative Hypothesis	Two-Sided
Power	0.90
Alpha	0.05
Group Allocation	Equal (N1 = N2)
Sample Size Per Group	40
Input Type	Difference
δ	Search > 0
σ	7
Reports Tab	

## **Output**

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

#### **Numeric Results**

**PASS Sample Size Software** 

Solve For: Effect Size (Means or Difference) Two-Sample Equal-Variance Z-Test Test Type:

Test Type: Two-Sample Equal-Varial Difference:  $\delta = \mu 1 - \mu 2$ Hypotheses: H0:  $\delta = 0$  vs. H1:  $\delta \neq 0$ 

	Sample Size		Mean Difference	Standard Deviation			
Power	N1	N2	N	δ	σ	Alpha	
0.9	40	40	80	5.074	7	0.05	

If the true population mean weight loss for one group is 5.074 lbs. more or less than the other, the researchers will have 90% power to show a difference between the groups.

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# Example 4 – Validation of Sample Size using Chow, Shao, and Wang (2008)

Chow, Show, and Wang (2008) pages 63 and 64 present an example for a two-sided test in which the mean difference is 0.05, the common standard deviation is known to be 0.10, the power is 80%, and the significance level is 0.05. They calculate the per group sample size as 63.

## 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.

Solve For	Sample Size	
Alternative Hypothesis	Two-Sided	
Power	0.80	
Alpha	0.05	
Group Allocation	Equal (N1 = N2)	
Input Type	Difference	
δ	0.05	
σ	0.1	

## **Output**

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

#### **Numeric Results**

Solve For: Sample Size

Test Type: Two-Sample Equal-Variance Z-Test

Difference:  $\delta = \mu 1 - \mu 2$ 

Hypotheses: H0:  $\delta = 0$  vs. H1:  $\delta \neq 0$ 

Pow	ver	Sample Size			Mean Difference	Standard Deviation		
Target	Actual	N1	N2	N	δ	σ	Alpha	
0.8	0.8013	63	63	126	0.05	0.1	0.05	

The sample size of 63 per group matches Chow, Show, and Wang's result exactly.