Chapter 745

Assurance for Tests for Two Means in a Cluster-Randomized Design

Introduction

This procedure calculates the assurance of two-sample t-tests when the variances of the two groups (populations) are assumed to be equal (Fisher, 1925) and the data are collected in a cluster-randomized design. The calculation is based on a user-specified prior distribution of the effect size parameters. This procedure may also be used to determine the needed sample size to obtain a specified assurance.

The methods for assurance calculation in this procedure are based on O'Hagan, Stevens, and Campbell (2005).

Cluster-randomized designs are those in which whole clusters of subjects (classes, hospitals, communities, etc.) are put into the treatment group or the control group. In this case, the means of two groups, made up of K_i clusters of M_{ij} individuals each, are to be tested using a t-test. The t-test can be calculated on the cluster means or the individual subject responses. Generally speaking, the larger the cluster sizes and the higher the correlation among subjects within the same cluster, the larger will be the overall sample size necessary to detect an effect with the same power.

Assurance

The assurance of a design is the expected value of the power with respect to one or more prior distributions of the design parameters. Assurance is also referred to as *Bayesian assurance*, *expected power*, *average power*, *statistical assurance*, *hybrid classical-Bayesian procedure,* or *probability of success*.

The power of a design is the probability of rejecting the null hypothesis, conditional on a given set of design attributes, such as the test statistic, the significance level, the sample size, and the effect size to be detected. As the effect size parameters are typically unknown quantities, the stated power may be very different from the true power if the specified parameter values are inaccurate.

While power is conditional on individual design parameter values, and is highly sensitive to those values, assurance is the average power across a presumed prior distribution of the effect size parameters. Thus, assurance adds a Bayesian element to the frequentist framework, resulting in a hybrid approach to the probability of trial or study success. It should be noted that when it comes time to perform the statistical test on the resulting data, these methods for calculating assurance assume that the traditional (frequentist) tests will be used.

The next section describes some of the ways in which the prior distributions for effect size parameters may be determined.

Elicitation

In order to calculate assurance, a suitable prior distribution for the effect size parameters must be determined. This process is called the *elicitation* of the prior distribution.

The elicitation may be as simple as choosing a distribution that seems plausible for the parameter(s) of interest, or as complex as combining the informed advice of several experts based on experience in the field, available pilot data, or previous studies. The accuracy of the assurance value depends on the accuracy of the elicited prior distribution. The assumption (or hope) is that an informed prior distribution will produce a more accurate estimate of the probability of trial success than a single value estimate. Because clinical trials and other studies are often costly, many institutions now routinely require an elicitation step.

Two reference texts that focus on elicitation are O'Hagan, Buck, Daneshkhah, Eiser, Garthwaite, Jenkinson, Oakley, and Rakow (2006) and Dias, Morton, and Quigley (2018).

Two-Sample T-Test

Our formulation comes from Campbell and Walters (2014) and Ahn, Heo, and Zhang (2015). Denote an observation by Y_{ijk} where i = 1, 2 gives the group, j = 1,2, ..., K_i gives the cluster within group i, and k = 1, 2, ..., m_{ij} denotes an individual in cluster j of group i.

We let σ^2 denote the variance of Y_{ijk}, which is $\sigma^2_{Between} + \sigma^2_{Within}$, where $\sigma^2_{Between}$ is the variation between clusters and σ^2_{Within} is the variation within clusters. Also, let ρ denote the intracluster correlation coefficient (ICC) which is $\sigma^2_{Between}/\left(\sigma^2_{Between} + \sigma^2_{Within}\right)$. This correlation is simply the correlation between any two observations in the same cluster.

For sample size calculation, we assume that the m_{ij} are distributed with a mean cluster size of M_i and a coefficient of variation cluster sizes of *COV*. The variances of the two group means, $\bar{Y}_i$, are approximated by

$$V_i = \frac{\sigma^2(DE_i)(RE_i)}{K_i M_i}$$

$$DE_i = 1 + (M_i - 1)\rho$$

$$RE_i = \frac{1}{1 - (COV)^2\lambda_i(1 - \lambda_i)}$$

$$\lambda_i = M_i\rho/(M_i\rho + 1 - \rho)$$

DE is called the *Design Effect* and RE is the *Relative Efficiency* of unequal to equal cluster sizes. Both are greater than or equal to one, so both inflate the variance.

Assume that $\delta = \mu_1 - \mu_2$ is to be tested using a t-test (small sample) or z-test (large sample). The statistical hypotheses for a two-sided hypothesis test are $H_0\colon \delta = 0$ vs. $H_1\colon \delta \neq 0$. The test statistic

$$t = \frac{\bar{Y}_1 - \bar{Y}_2}{\sqrt{\hat{V}_1 + \hat{V}_2}}$$

has an approximate t distribution with degrees of freedom $DF = K_1M_1 + K_2M_2 - 2$ for a *subject-level* analysis or $K_1 + K_2 - 2$ for a *cluster-level* analysis.

Let the noncentrality parameter $\Delta = \delta/\sigma_d$, where $\sigma_d = \sqrt{V_1 + V_2}$. We can define the two critical values based on a central t-distribution with DF degrees of freedom as follows.

$$X_1 = t_{\frac{\alpha}{2},DF}$$

$$X_2 = t_{1-\frac{\alpha}{2},DF}$$

The power can be found from the following to probabilities

$$P_1 = H_{X_1,DF,\Delta}$$

$$P_2 = H_{X_2,DF,\Delta}$$

$$Power = 1 - (P_2 - P_1)$$

where $H_{X,DF,\Delta}$ is the cumulative probability distribution of the noncentral-t distribution.

The power of a one-sided test can be calculated similarly.

Assurance Calculation

The assurance computation described here is based on O'Hagan, Stevens, and Campbell (2005).

Let $P_1(H|\delta,\sigma,\rho,M_1,M_2,COV)$ be the power function described above where H is the event that null hypothesis is rejected conditional on the values of the parameters. The specification of the parameters is critical to the power calculation, but the actual values are seldom known. Assurance is defined as the expected power where the expectation is with respect to a joint prior distribution for the parameters. Hence, the definition of assurance is

$$Assurance = E_{\delta,\sigma,\rho,M_1,M_2,COV}\left(P_1(H|\delta,\sigma,\rho,M_1,M_2,COV)\right)$$

$$= \int\int\int\int\int\int P_1(H|\delta,\sigma,\rho,M_1,M_2,COV) f(\delta,\sigma,\rho,M_1,M_2,COV) d\delta \dots dCOV$$

where $f(\delta,\sigma,\rho,M_1,M_2,COV)$ is the joint prior distribution of the parameters.

In **PASS**, the joint prior distribution can be specified as either a discrete approximation to the joint prior distribution, or as individual prior distributions, one for each parameter.

Specifying a Joint Prior Distribution

If the joint prior distribution is to be specified directly, the distribution is specified in **PASS** using a discrete approximation to the function $f(\delta,\sigma,\rho,M_1,M_2,COV)$. This provides flexibility in specifying the joint prior distribution. In the six-parameter case, seven columns are entered on the spreadsheet: six for the parameters and one more for the probability. Each row gives a value for each parameter and the corresponding parameter-combination probability. The accuracy of the distribution approximation is controlled by the number of points (spreadsheet rows) that are used.

An example of entering a joint prior distribution is included at the end of the chapter.

Specifying Individual Prior Distributions

Ciarleglio, Arendt, and Peduzzi (2016) suggest that more flexibility is available if the joint prior distribution is separated into two independent distributions as follows:

$$f(\delta, \sigma, \rho, M_1, M_2, COV) = f_1(\delta) f_2(\sigma) f_3(\rho) f_4(M_1) f_5(M_2) f_6(COV)$$

where $f_1(\delta)$ is the prior distribution of δ and so forth. This method is also available in **PASS**. In this case, the definition of assurance becomes

$$Assurance = E_{\delta,\sigma,\rho,M_1,M_2,COV}\big(P_1(H|\delta, \sigma, \rho, M_1, M_2, COV)\big)$$

$$= \int\int\int\int\int\int P_1(H|\delta, \sigma, \rho, M_1, M_2, COV) f_1(\delta) f_2(\sigma) f_3(\rho) f_4(M_1) f_5(M_2) f_6(COV) d\delta \ldots dCOV$$

Using this definition, the assurance can be calculated using numerical integration. There are a variety of pre-programmed, univariate prior distributions available in **PASS**.

Fixed Values (No Prior) and Custom Values

For any given parameter, **PASS** also provides the option of entering a single fixed value for the prior distribution, or a series of values and corresponding probabilities (using the spreadsheet), rather than one of the pre-programmed distributions.

Numerical Integration in PASS (and Notes on Computation Speed)

When the prior distribution is specified as independent univariate distributions, **PASS** uses a numerical integration algorithm to compute the assurance value as follows:

The domain of each prior distribution is divided into *M* intervals. Since many of the available prior distributions are unbounded on one (e.g., Gamma) or both (e.g., Normal) ends, an approximation is made to make the domain finite. This is accomplished by truncating the distribution to a domain between the two quantiles: $q_{0.001}$ and $q_{0.999}$.

The value of *M* controls the accuracy and speed of the algorithm. If only one parameter is to be given a prior distribution, then a value of *M* between 50 and 100 usually gives an accurate result in a timely manner. However, if two parameters are given priors, the number of iterations needed increases from M to M^2. For example, if *M* is 100, 10000 iterations are needed. Reducing *M* from 100 to 50 reduces the number of iterations from 10000 to 2500.

The algorithm runtime increases when searching for sample size rather than solving for assurance, as a search algorithm is employed in this case. When solving for sample size, we recommend reducing *M* to 20 or less while exploring various scenarios, and then increasing *M* to 50 or more for a final, more accurate, result.

List of Available Univariate Prior Distributions

This section lists the univariate prior distributions that may be used for any of the applicable parameters when the Prior Entry Method is set to Individual.

No Prior

If 'No Prior' is chosen for a parameter, the parameter is assumed to take on a single, fixed value with probability one.

Beta (Shape 1, Shape 2, a, c)

A random variable *X* that follows the beta distribution is defined on a finite interval [a, c]. Two shape parameters (α and β) control the shape of this distribution. Two location parameters *a* and *c* give the minimum and maximum of *X*.

The probability density function of the beta distribution is

$$f(x|\alpha,\beta,a,c) = \frac{\left(\frac{x-a}{c-a}\right)^{\alpha-1}\left(\frac{c-x}{c-a}\right)^{\beta-1}}{(c-a)B(\alpha,\beta)}$$

where $B(\alpha,\beta) = \Gamma(\alpha)\,\Gamma(\beta)/\,\Gamma(\alpha+\beta)$ and $\Gamma(z)$ is the gamma function.

The mean of *X* is

$$\mu_X = \frac{\alpha c + \beta a}{\alpha + \beta}$$

Various distribution shapes are controlled by the values of α and β. These include

Symmetric and Unimodal

$$\alpha = \beta > 1$$

U Shaped

$$\alpha = \beta < 1$$

Bimodal

$$\alpha, \beta < 1$$

Uniform

$$\alpha = \beta = 1$$

Parabolic

$$\alpha = \beta = 2$$

Bell-Shaped

$$\alpha = \beta > 2$$

Gamma (Shape, Scale)

A random variable *X* that follows the gamma distribution is defined on the interval $(0, \infty)$. A shape parameter, κ, and a scale parameter, θ, control the distribution.

The probability density function of the gamma distribution is

$$f(x|\kappa, \theta) = \frac{x^{\kappa-1}e^{-\frac{x}{\theta}}}{\theta^{\kappa}\Gamma(\kappa)}$$

where $\Gamma(z)$ is the gamma function.

The mean of *X* is

$$\mu_X = \frac{\kappa}{\theta}$$

A truncated version of the distribution is constructed by dividing the density by $1 - \text{Prob}(Min \leq X \leq Max)$ where *Min* and *Max* are two truncation bounds.

Inverse-Gamma (Shape, Scale)

A random variable *X* that follows the inverse-gamma distribution is defined on the interval $(0, \infty)$. If *Y* ~ gamma, then *X* = 1 / *Y* ~ inverse-gamma. A shape parameter, α, and a scale parameter, β, control the distribution.

The probability density function of the inverse-gamma distribution is

$$f(x|\alpha, \beta) = \frac{\beta^{\alpha}x^{\alpha-1}e^{-\frac{\beta}{x}}}{\Gamma(\alpha)}$$

where $\Gamma(z)$ is the gamma function.

The mean of *X* is

$$\mu_X = \frac{\beta}{\alpha - 1} \text{ for } \alpha > 1$$

A truncated version of the distribution is constructed by dividing the density by $1 - \text{Prob}(Min \leq X \leq Max)$ where *Min* and *Max* are two truncation bounds.

Logistic (Location, Scale)

A random variable *X* that follows the logistic distribution is defined on the interval $(-\infty, \infty)$. A location parameter, μ, and a scale parameter, s, control the distribution.

The probability density function of the logistic distribution is

$$f(x|\mu, s) = \frac{e^{-\frac{x-\mu}{s}}}{\text{s}\left(1 + e^{-\frac{x-\mu}{s}}\right)^2}$$

The mean of *X* is

$$\mu_X = \mu$$

A truncated version of the distribution is constructed by dividing the density by $1 - \text{Prob}(Min \leq X \leq Max)$ where *Min* and *Max* are two truncation bounds.

Lognormal (Mean, SD)

A random variable *X* that follows the lognormal distribution is defined on the interval $(0, \infty)$. A location parameter, $\mu_{\log(X)}$, and a scale parameter, $\sigma_{\log(X)}$, control the distribution. If Z ~ standard normal, then $X = e^{\mu+\sigma Z} \sim$ lognormal. Note that $\mu_{\log(X)} = E(\log(X))$ and $\sigma_{\log(X)} = Standard\ Deviation(\log(X))$.

The probability density function of the lognormal distribution is

$$f(x|\mu, \sigma) = \frac{e^{-\frac{1}{2}\left(\frac{\log x-\mu}{\sigma}\right)^2}}{x\sigma\sqrt{2\pi}}$$

The mean of *X* is

$$\mu_X = e^{\mu+\frac{\sigma^2}{2}}$$

A truncated version of the distribution is constructed by dividing the density by $1 - \text{Prob}(Min \leq X \leq Max)$ where *Min* and *Max* are two truncation bounds.

LogT (Mean, SD)

A random variable *X* that follows the logT distribution is defined on the interval $(0, \infty)$. A location parameter, $\mu_{\log(X)}$, a scale parameter, $\sigma_{\log(X)}$, and a shape parameter, ν, control the distribution. Note that ν is referred to as the *degrees of freedom*.

If t ~ Student's t, then $X = e^{\mu+\sigma t} \sim$ logT.

The probability density function of the logT distribution is

$$f(x|\mu,\sigma,\nu) = \frac{\Gamma\left(\frac{\nu+1}{2}\right)}{x\Gamma\left(\frac{\nu}{2}\right)\sigma\sqrt{\nu\pi}}\left(1+\frac{1}{\nu}\left(\frac{\log x-\mu}{\sigma}\right)^2\right)^{\left(\frac{-\nu-1}{2}\right)}$$

The mean of *X* is not defined.

A truncated version of the distribution is constructed by dividing the density by $1 - \text{Prob}(Min \le X \le Max)$ where *Min* and *Max* are two truncation bounds.

Normal (Mean, SD)

A random variable *X* that follows the normal distribution is defined on the interval $(-\infty, \infty)$. A location parameter, μ, and a scale parameter, σ, control the distribution.

The probability density function of the normal distribution is

$$f(x|\mu,\sigma) = \frac{e^{-\frac{1}{2}\left(\frac{x-\mu}{\sigma}\right)^2}}{\sigma\sqrt{2\pi}}$$

The mean of *X* is

$$\mu_X = \mu$$

A truncated version of the distribution is constructed by dividing the density by $1 - \text{Prob}(Min \le X \le Max)$ where *Min* and *Max* are two truncation bounds.

T (Mean, SD, DF)

A random variable *X* that follows Student's t distribution is defined on the interval $(-\infty, \infty)$. A location parameter, μ, a scale parameter, σ, and a shape parameter, ν, control the distribution. Note that ν is referred to as the *degrees of freedom* or *DF*.

The probability density function of the Student's t distribution is

$$f(x|\mu,\sigma,\nu) = \frac{\Gamma\left(\frac{\nu+1}{2}\right)}{\Gamma\left(\frac{\nu}{2}\right)\sigma\sqrt{\nu\pi}}\left(1+\frac{1}{\nu}\left(\frac{x-\mu}{\sigma}\right)^2\right)^{\left(\frac{-\nu-1}{2}\right)}$$

The mean of *X* is μ if $\nu > 1$.

A truncated version of the distribution is constructed by dividing the density by $1 - \text{Prob}(Min \le X \le Max)$ where *Min* and *Max* are two truncation bounds.

Triangle (Mode, Min, Max)

Let *a* = minimum, *b* = maximum, and *c* = mode. A random variable *X* that follows a triangle distribution is defined on the interval (a, b).

The probability density function of the triangle distribution is

$$f(x|a,b,c) = \begin{cases} \dfrac{2(x-a)}{(b-a)(c-a)} & \text{for } a \leq x < c \\ \dfrac{2}{b-a} & \text{for } x = c \\ \dfrac{2(b-x)}{(b-a)(b-c)} & \text{for } c < x \leq b \end{cases}$$

The mean of *X* is

$$\frac{a+b+c}{3}$$

Uniform (Min, Max)

Let *a* = minimum and *b* = maximum. A random variable *X* that follows a uniform distribution is defined on the interval $[a, b]$.

The probability density function of the uniform distribution is

$$f(x|a,b) = \begin{cases} \dfrac{1}{b-a} & \text{for } a \leq x \leq b \end{cases}$$

The mean of *X* is

$$\frac{a+b}{2}$$

Weibull (Shape, Scale)

A random variable *X* that follows the Weibull distribution is defined on the interval $(0, \infty)$. A shape parameter, κ, and a scale parameter, λ, control the distribution.

The probability density function of the Weibull distribution is

$$f(x|\kappa,\lambda) = \frac{\kappa}{\lambda}\left(\frac{x}{\lambda}\right)^{\kappa-1} e^{-\left(\frac{x}{\lambda}\right)^{\kappa}}$$

The mean of *X* is

$$\mu_X = \kappa\Gamma\left(1 + \frac{1}{\kappa}\right)$$

A truncated version of the distribution is constructed by dividing the density by $1 - \text{Prob}(Min \leq X \leq Max)$ where *Min* and *Max* are two truncation bounds.

Custom (Values and Probabilities in Spreadsheet)

This custom prior distribution is represented by a set of user-specified points and associated probabilities, entered in two columns of the spreadsheet. The points make up the entire set of values that are used for this parameter in the calculation of assurance. The associated probabilities should sum to one. Note that custom values and probabilities can be used to approximate any continuous distribution.

For example, a prior distribution of X might be

X_i	P_i
10	0.2
20	0.2
30	0.3
40	0.2
50	0.1

In this example, the mean of X is

$$\mu_X = \sum_{i=1}^{5} X_i P_i$$

Example 1 – Assurance Over a Range of Sample Sizes

Suppose that a cluster randomized study is being planned in which δ = 1; σ = 2; ρ = 0.01; *M1* and *M2* = 5 or 10; *COV* = 0.65; *alpha* = 0.05; and *K1* and *K2* = 5 to 20 by 5. Power is to be calculated for a two-sided, subject-level test.

To complete their sample size study, the researchers want to run an assurance analysis for a range of group sample sizes from 5 to 20. An elicitation exercise determined that the prior distribution of the mean difference should be normal with mean 1 and standard deviation 0.1, the prior distribution of the common group standard deviation should be a normal with mean 2 and standard deviation 0.2, the prior distribution of the ICC should be a normal with mean 0.01 and standard deviation 0.002, the prior distribution of the cluster size of group 1 should be a normal with mean 7.5 and standard deviation 1.5, the prior distribution of the cluster size of group 2 should be a normal with mean 7.5 and standard deviation 1.5, and the prior distribution of the coefficient of variation of cluster sizes should be a normal with mean 0.65 and standard deviation 0.05.

To reduce the runtime of this example, the number of computation points is set to 4. In practice, we recommend setting this value to 10 or more for the most accurate results.

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	**Assurance**
Prior Entry Method	**Individual (Enter a prior distribution for each applicable parameter)**
Alternative Hypothesis	**Two-Sided (H1: δ ≠ 0)**
Test Statistic	**T-Test Based on Number of Subjects**
Alpha	**0.05**
K1 (Number of Clusters)	**5 10 15 20**
Prior Distribution of M1	**Normal (Mean, SD)**
Mean	**7.5**
SD	**1.5**
Truncation Boundaries	**None**
K2 (Number of Clusters)	**K1**
Prior Distribution of M2	**Normal (Mean, SD)**
Mean	**7.5**
SD	**1.5**
Truncation Boundaries	**None**
Prior Distribution of COV	**Normal (Mean, SD)**
Mean	**0.65**
SD	**0.05**
Truncation Boundaries	**None**

Prior Distribution of δ....................................**Normal (Mean, SD)**
Mean..**1**
SD...**0.1**
Truncation Boundaries..................................**None**
Prior Distribution of σ....................................**Normal (Mean, SD)**
Mean..**2**
SD...**0.2**
Truncation Boundaries..................................**None**
Prior Distribution of ρ....................................**Normal (Mean, SD)**
Mean..**0.01**
SD...**0.002**
Truncation Boundaries..................................**None**

Options Tab

Number of Computation Points for each Prior Distribution........**4**
Maximum K1 in Sample Size Search............**1000**

Output

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

Numeric Reports

Numeric Results

Solve For: Assurance
Groups: 1 = Treatment, 2 = Control
Test Statistic: T-Test with DF based on number of subjects
Hypotheses: H0: δ = 0 vs. H1: δ ≠ 0
Prior Type: Individual Univariate Distributions

Prior Distributions
M1: Normal (Mean = 7.5, SD = 1.5).
M2: Normal (Mean = 7.5, SD = 1.5).
COV: Normal (Mean = 0.65, SD = 0.05).
δ: Normal (Mean = 1, SD = 0.1).
σ: Normal (Mean = 2, SD = 0.2).
ρ: Normal (Mean = 0.01, SD = 0.002).

		Sample Size			Number of Clusters			Cluster Size			Mean Difference	Standard Deviation	Intracluster Correlation	
Assurance*	Power‡	N1	N2	N	K1	K2	K	E(M1)	E(M2)	E(COV)	E(δ)	E(σ)	E(ρ)	Alpha
0.53226	0.53805	38	38	76	5	5	10	7.5	7.5	0.65	1	2	0.01	0.05
0.80107	0.83303	76	76	152	10	10	20	7.5	7.5	0.65	1	2	0.01	0.05
0.91581	0.94692	113	113	226	15	15	30	7.5	7.5	0.65	1	2	0.01	0.05
0.96358	0.98530	151	151	302	20	20	40	7.5	7.5	0.65	1	2	0.01	0.05

* The number of points used for computation of the prior(s) was 4.
‡ Power was calculated using M1 = E(M1) = 7.5, M2 = E(M2) = 7.5, COV = E(COV) = 0.65, δ = E(δ) = 1, σ = E(σ) = 2, and ρ = E(ρ) = 0.01.

Assurance	The expected power where the expectation is with respect to the prior distribution(s).
Power	The power calculated using the means of the prior distributions as the values of the corresponding parameters.
N1	The number of subjects in group 1.
N2	The number of subjects in group 2.
N	The total sample size. N = N1 + N2.
K1	The number of clusters in group 1.
K2	The number of clusters in group 2.
K	The total number of clusters.
E(M1)	The expected average number of items (subjects) per cluster in group 1.
E(M2)	The expected average number of items (subjects) per cluster in group 2.
E(COV)	The expected coefficient of variation of the cluster sizes.
E(δ)	The expected mean difference in the response assumed by H1. δ = μ1 - μ2.
E(σ)	The expected standard deviation of the subject responses.
E(ρ)	The expected intracluster correlation (ICC).
Alpha	The probability of rejecting a true null hypothesis.

Summary Statements

A parallel two-group cluster-randomized design will be used to test whether the Group 1 (treatment) mean (μ1) is different from the Group 2 (control) mean (μ2) (H0: δ = 0 versus H1: δ ≠ 0, δ = μ1 - μ2). The comparison will be made using a two-sided t-test with degrees of freedom based on the number of subjects (as in a subject-level analysis), and with a Type I error rate (α) of 0.05. The prior distribution used for the average cluster size in Group 1 is Normal (Mean = 7.5, SD = 1.5). The prior distribution used for the average cluster size in Group 2 is Normal (Mean = 7.5, SD = 1.5). The prior distribution used for the coefficient of variation of cluster sizes is Normal (Mean = 0.65, SD = 0.05). The prior distribution used for the difference between the group means is Normal (Mean = 1, SD = 0.1). The prior distribution used for the standard deviation of subjects is Normal (Mean = 2, SD = 0.2). The prior distribution used for the intracluster correlation coefficient is Normal (Mean = 0.01, SD = 0.002). With 5 clusters (38 total subjects) in Group 1 (treatment) and 5 clusters (38 total subjects) in Group 2 (control), the assurance (average power) is 0.53226.

References

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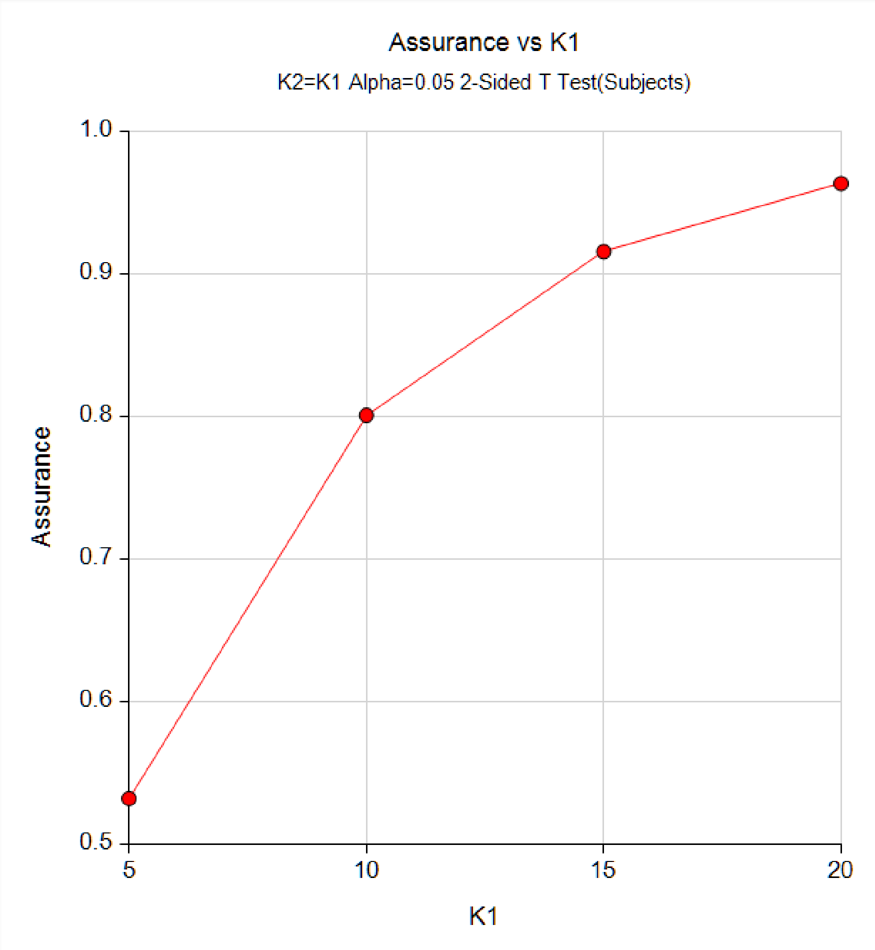
Donner, A. and Klar, N. 2000. Design and Analysis of Cluster Randomization Trials in Health Research. Arnold. London.

Chow, S.C., Shao, J., Wang, H., and Lokhnygina, Y. 2018. Sample Size Calculations in Clinical Research, Third Edition. Taylor & Francis/CRC. Boca Raton, Florida.

This report shows the assurance values obtained by the various sample sizes.

Plots Section

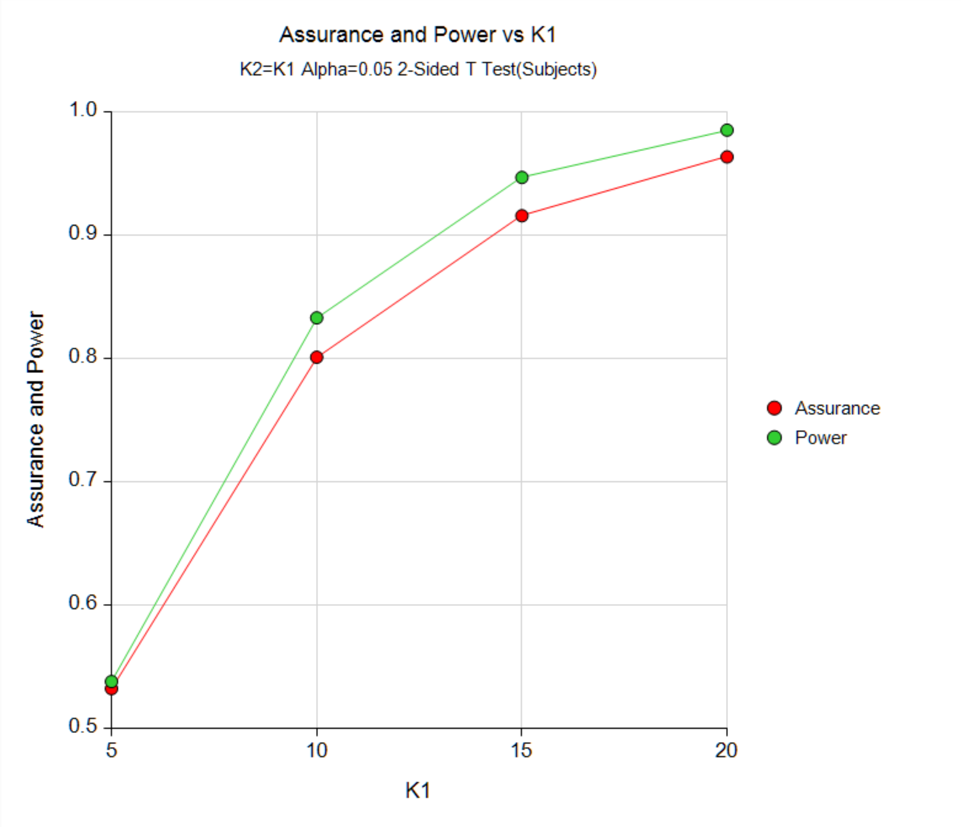
Plots



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

Comparison Plots Section

Comparison Plots



This plot compares the assurance and power across values of sample size.

Example 2 – Validation using Hand Computation

We could not find a validation example in the literature for procedure, so we have developed a validation example of our own.

Suppose a two-sided, two-sample t-test will be used in which K1 = K2 = 30 and the significance level is 0.05.

The prior distribution of δ is approximated by the following table. These are loaded into C1 and C2.

δ	Prob
-0.3	0.4
0.7	0.6

The prior distribution of the σ is approximated by the following table. These are loaded into C3 and C4.

σ	Prob
1.5	0.4
2.5	0.6

The prior distribution of the ρ is approximated by the following table. These are loaded into C5 and C6.

ρ	Prob
0.01	0.5
0.02	0.5

The prior distribution of the M1 is approximated by the following table. These are loaded into C7 and C8.

M1	Prob
7	0.5
9	0.5

The prior distribution of the M2 is approximated by the following table. These are loaded into C9 and C10.

M2	Prob
7	0.5
9	0.5

The prior distribution of the COV is approximated by the following table. These are loaded into C11 and 12.

COV	Prob
0.6	0.3
0.7	0.7

To run this example, the spreadsheet will need to be loaded with the following 12 columns corresponding to the values listed above.

C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12
-0.3	0.4	1.5	0.4	0.01	0.5	7	0.5	7	0.5	0.6	0.3
0.7	0.6	2.5	0.6	0.02	0.5	9	0.5	9	0.5	0.7	0.7

The *Tests for Two Means in a Cluster-Randomized Design* procedure is used to compute the power for each of the 64 combinations the parameters. The results of these calculations are shown next.

Numeric Results for a Test of Mean Difference

Solve For: Power
Groups: 1 = Treatment, 2 = Control
Test Statistic: T-Test with DF based on number of subjects
Hypotheses: H0: δ = 0 vs. H1: δ ≠ 0

	Number of Clusters			Cluster Size			Sample Size			Mean Difference	Standard Deviation	ICC	
Power	K1	K2	K	M1	M2	COV	N1	N2	N	δ	σ	ρ	Alpha
0.50157	30	30	60	7	7	0.6	210	210	420	-0.3	1.5	0.01	0.05
0.49836	30	30	60	7	7	0.7	210	210	420	-0.3	1.5	0.01	0.05
0.54482	30	30	60	7	9	0.6	210	270	480	-0.3	1.5	0.01	0.05
0.54108	30	30	60	7	9	0.7	210	270	480	-0.3	1.5	0.01	0.05
0.54482	30	30	60	9	7	0.6	270	210	480	-0.3	1.5	0.01	0.05
0.54108	30	30	60	9	7	0.7	270	210	480	-0.3	1.5	0.01	0.05
0.59532	30	30	60	9	9	0.6	270	270	540	-0.3	1.5	0.01	0.05
0.59095	30	30	60	9	9	0.7	270	270	540	-0.3	1.5	0.01	0.05
0.47361	30	30	60	7	7	0.6	210	210	420	-0.3	1.5	0.02	0.05
0.46802	30	30	60	7	7	0.7	210	210	420	-0.3	1.5	0.02	0.05
0.51199	30	30	60	7	9	0.6	210	270	480	-0.3	1.5	0.02	0.05
0.50554	30	30	60	7	9	0.7	210	270	480	-0.3	1.5	0.02	0.05
0.51199	30	30	60	9	7	0.6	270	210	480	-0.3	1.5	0.02	0.05
0.50554	30	30	60	9	7	0.7	270	210	480	-0.3	1.5	0.02	0.05
0.55662	30	30	60	9	9	0.6	270	270	540	-0.3	1.5	0.02	0.05
0.54915	30	30	60	9	9	0.7	270	270	540	-0.3	1.5	0.02	0.05
0.21805	30	30	60	7	7	0.6	210	210	420	-0.3	2.5	0.01	0.05
0.21664	30	30	60	7	7	0.7	210	210	420	-0.3	2.5	0.01	0.05
0.23753	30	30	60	7	9	0.6	210	270	480	-0.3	2.5	0.01	0.05
0.23580	30	30	60	7	9	0.7	210	270	480	-0.3	2.5	0.01	0.05
0.23753	30	30	60	9	7	0.6	270	210	480	-0.3	2.5	0.01	0.05
0.23580	30	30	60	9	7	0.7	270	210	480	-0.3	2.5	0.01	0.05
0.26184	30	30	60	9	9	0.6	270	270	540	-0.3	2.5	0.01	0.05
0.25966	30	30	60	9	9	0.7	270	270	540	-0.3	2.5	0.01	0.05
0.20601	30	30	60	7	7	0.6	210	210	420	-0.3	2.5	0.02	0.05
0.20365	30	30	60	7	7	0.7	210	210	420	-0.3	2.5	0.02	0.05
0.22264	30	30	60	7	9	0.6	210	270	480	-0.3	2.5	0.02	0.05
0.21979	30	30	60	7	9	0.7	210	270	480	-0.3	2.5	0.02	0.05
0.22264	30	30	60	9	7	0.6	270	210	480	-0.3	2.5	0.02	0.05
0.21979	30	30	60	9	7	0.7	270	210	480	-0.3	2.5	0.02	0.05
0.24304	30	30	60	9	9	0.6	270	270	540	-0.3	2.5	0.02	0.05
0.23954	30	30	60	9	9	0.7	270	270	540	-0.3	2.5	0.02	0.05
0.99563	30	30	60	7	7	0.6	210	210	420	0.7	1.5	0.01	0.05
0.99538	30	30	60	7	7	0.7	210	210	420	0.7	1.5	0.01	0.05
0.99799	30	30	60	7	9	0.6	210	270	480	0.7	1.5	0.01	0.05
0.99784	30	30	60	7	9	0.7	210	270	480	0.7	1.5	0.01	0.05
0.99799	30	30	60	9	7	0.6	270	210	480	0.7	1.5	0.01	0.05
0.99784	30	30	60	9	7	0.7	270	210	480	0.7	1.5	0.01	0.05
0.99925	30	30	60	9	9	0.6	270	270	540	0.7	1.5	0.01	0.05
0.99918	30	30	60	9	9	0.7	270	270	540	0.7	1.5	0.01	0.05
0.99302	30	30	60	7	7	0.6	210	210	420	0.7	1.5	0.02	0.05
0.99236	30	30	60	7	7	0.7	210	210	420	0.7	1.5	0.02	0.05
0.99635	30	30	60	7	9	0.6	210	270	480	0.7	1.5	0.02	0.05
0.99592	30	30	60	7	9	0.7	210	270	480	0.7	1.5	0.02	0.05
0.99635	30	30	60	9	7	0.6	270	210	480	0.7	1.5	0.02	0.05
0.99592	30	30	60	9	7	0.7	270	210	480	0.7	1.5	0.02	0.05
0.99839	30	30	60	9	9	0.6	270	270	540	0.7	1.5	0.02	0.05
0.99814	30	30	60	9	9	0.7	270	270	540	0.7	1.5	0.02	0.05
0.78505	30	30	60	7	7	0.6	210	210	420	0.7	2.5	0.01	0.05
0.78173	30	30	60	7	7	0.7	210	210	420	0.7	2.5	0.01	0.05
0.82678	30	30	60	7	9	0.6	210	270	480	0.7	2.5	0.01	0.05
0.82337	30	30	60	7	9	0.7	210	270	480	0.7	2.5	0.01	0.05
0.82678	30	30	60	9	7	0.6	270	210	480	0.7	2.5	0.01	0.05
0.82337	30	30	60	9	7	0.7	270	210	480	0.7	2.5	0.01	0.05
0.86900	30	30	60	9	9	0.6	270	270	540	0.7	2.5	0.01	0.05
0.86561	30	30	60	9	9	0.7	270	270	540	0.7	2.5	0.01	0.05

0.75525	30	30	60	7	7	0.6	210	210	420	0.7	2.5	0.02	0.05
0.74902	30	30	60	7	7	0.7	210	210	420	0.7	2.5	0.02	0.05
0.79558	30	30	60	7	9	0.6	210	270	480	0.7	2.5	0.02	0.05
0.78909	30	30	60	7	9	0.7	210	270	480	0.7	2.5	0.02	0.05
0.79558	30	30	60	9	7	0.6	270	210	480	0.7	2.5	0.02	0.05
0.78909	30	30	60	9	7	0.7	270	210	480	0.7	2.5	0.02	0.05
0.83726	30	30	60	9	9	0.6	270	270	540	0.7	2.5	0.02	0.05
0.83067	30	30	60	9	9	0.7	270	270	540	0.7	2.5	0.02	0.05

The assurance calculation is made by summing the quantities

$$[(power_{i,j,k,l,m,n})p(\delta_i)p(\sigma_j)p(\rho_k)p(M1_l)p(M2_m)p(COV_n)]$$

as follows

$$\begin{aligned} Assurance &= (0.50157 \times 0.4 \times 0.4 \times 0.5 \times 0.5 \times 0.5 \times 0.3) + (0.49836 \times 0.4 \times 0.4 \times 0.5 \times 0.5 \times 0.5 \times 0.7) \\ &\quad + \cdots + (0.83067 \times 0.6 \times 0.6 \times 0.5 \times 0.5 \times 0.5 \times 0.7) \\ &= 0.66940. \end{aligned}$$

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 .... **Assurance**
Prior Entry Method.. **Individual (Enter a prior distribution for each applicable parameter)**
Alternative Hypothesis .... **Two-Sided (H1: δ ≠ 0)**
Test Statistic .... **T-Test Based on Number of Subjects**
Alpha.. **0.05**
K1 (Number of Clusters) **30**
Prior Distribution of M1 .... **Custom (Values and Probabilities in Spreadsheet)**
Column of Values **C7**
Column of Pr(Values).................................... **C8**
K2 (Number of Clusters) **30**
Prior Distribution of M2 .... **Custom (Values and Probabilities in Spreadsheet)**
Column of Values **C9**
Column of Pr(Values).................................... **C10**

Prior Distribution of COV................................**Custom (Values and Probabilities in Spreadsheet)**
Column of Values **C11**
Column of Pr(Values)....................................**C12**
Prior Distribution of δ ....**Custom (Values and Probabilities in Spreadsheet)**
Column of Values **C1**
Column of Pr(Values)....................................**C2**
Prior Distribution of σ ....**Custom (Values and Probabilities in Spreadsheet)**
Column of Values **C3**
Column of Pr(Values)....................................**C4**
Prior Distribution of ρ ....**Custom (Values and Probabilities in Spreadsheet)**
Column of Values **C5**
Column of Pr(Values)....................................**C6**

Options Tab

Number of Computation Points for each Prior Distribution........**4**
Maximum K1 in Sample Size Search.............**1000**

Input Spreadsheet Data

Row	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12
1	-0.3	0.4	1.5	0.4	0.01	0.5	7	0.5	7	0.5	0.6	0.3
2	0.7	0.6	2.5	0.6	0.02	0.5	9	0.5	9	0.5	0.7	0.7

Output

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

Numeric Results

Solve For: Assurance
Groups: 1 = Treatment, 2 = Control
Test Statistic: T-Test with DF based on number of subjects
Hypotheses: H0: δ = 0 vs. H1: δ ≠ 0
Prior Type: Individual Univariate Distributions

Prior Distributions
M1: Point List (Values = C7, Probs = C8).
C7: 7 9
C8: 0.5 0.5
M2: Point List (Values = C9, Probs = C10).
C9: 7 9
C10: 0.5 0.5
COV: Point List (Values = C11, Probs = C12).
C11: 0.6 0.7
C12: 0.3 0.7
δ: Point List (Values = C1, Probs = C2).
C1: -0.3 0.7
C2: 0.4 0.6
σ: Point List (Values = C3, Probs = C4).
C3: 1.5 2.5
C4: 0.4 0.6
ρ: Point List (Values = C5, Probs = C6).
C5: 0.01 0.02
C6: 0.5 0.5

		Sample Size			Number of Clusters			Cluster Size			Mean Difference	Standard Deviation	Intracluster Correlation	
Assurance	Power‡	N1	N2	N	K1	K2	K	E(M1)	E(M2)	E(COV)	E(δ)	E(σ)	E(ρ)	Alpha
0.6694	0.30644	240	240	480	30	30	60	8	8	0.67	0.3	2.1	0.015	0.05

‡ Power was calculated using M1 = E(M1) = 8, M2 = E(M2) = 8, COV = E(COV) = 0.67, δ = E(δ) = 0.3, σ = E(σ) = 2.1, and ρ = E(ρ) = 0.015.

PASS has also calculated the assurance as 0.6694 which validates the procedure.

Example 3 – Finding the Sample Size Needed to Achieve a Specified Assurance

Continuing with Example 1, the researchers want to investigate the sample sizes necessary to achieve assurances of 0.5, 0.6, and 0.7.

In order to reduce the runtime during this exploratory phase of the analysis, the number of points in the prior computation is reduced to 4. This slightly reduces the accuracy, but greatly reduces the runtime.

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**
Prior Entry Method	**Individual (Enter a prior distribution for each applicable parameter)**
Alternative Hypothesis	**Two-Sided (H1: δ ≠ 0)**
Test Statistic	**T-Test Based on Number of Subjects**
Assurance	**0.5 0.6 0.7**
Alpha	**0.05**
Prior Distribution of M1	**Normal (Mean, SD)**
Mean	**7.5**
SD	**1.5**
Truncation Boundaries	**None**
K2 (Number of Clusters)	**K1**
Prior Distribution of M2	**Normal (Mean, SD)**
Mean	**7.5**
SD	**1.5**
Truncation Boundaries	**None**
Prior Distribution of COV	**Normal (Mean, SD)**
Mean	**0.65**
SD	**0.05**
Truncation Boundaries	**None**
Prior Distribution of δ	**Normal (Mean, SD)**
Mean	**1**
SD	**0.1**
Truncation Boundaries	**None**
Prior Distribution of σ	**Normal (Mean, SD)**
Mean	**2**
SD	**0.2**
Truncation Boundaries	**None**

Prior Distribution of ρ ....**Normal (Mean, SD)**
Mean...**0.01**
SD...**0.002**
Truncation Boundaries..................................**None**

Options Tab

Number of Computation Points for each Prior Distribution........**4**
Maximum K1 in Sample Size Search............**1000**

Output

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

Numeric Reports

Numeric Results

Solve For: Sample Size
Groups: 1 = Treatment, 2 = Control
Test Statistic: T-Test with DF based on number of subjects
Hypotheses: H0: δ = 0 vs. H1: δ ≠ 0
Prior Type: Individual Univariate Distributions

Prior Distributions
M1: Normal (Mean = 7.5, SD = 1.5).
M2: Normal (Mean = 7.5, SD = 1.5).
COV: Normal (Mean = 0.65, SD = 0.05).
δ: Normal (Mean = 1, SD = 0.1).
σ: Normal (Mean = 2, SD = 0.2).
ρ: Normal (Mean = 0.01, SD = 0.002).

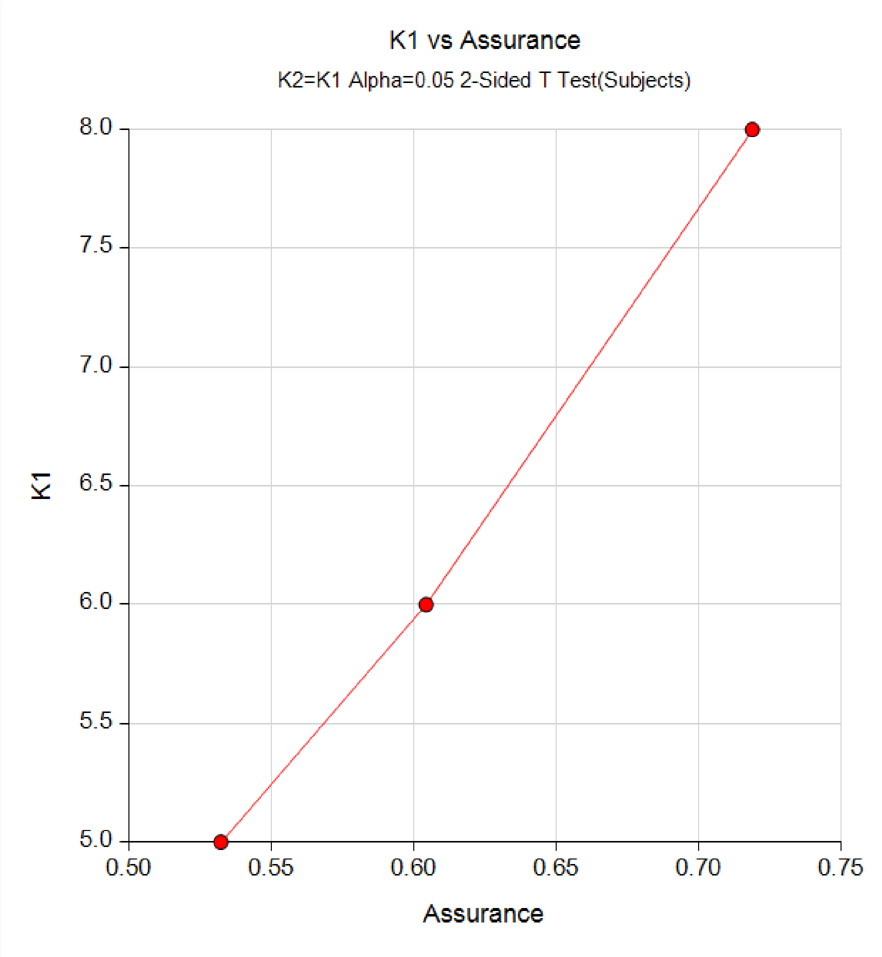
		Sample Size			Number of Clusters			Cluster Size			Mean Difference	Standard Deviation	Intracluster Correlation	
Assurance*	Power‡	N1	N2	N	K1	K2	K	E(M1)	E(M2)	E(COV)	E(δ)	E(σ)	E(ρ)	Alpha
0.53226	0.53805	38	38	76	5	5	10	7.5	7.5	0.65	1	2	0.01	0.05
0.60430	0.62050	46	46	92	6	6	12	7.5	7.5	0.65	1	2	0.01	0.05
0.71879	0.74452	61	61	122	8	8	16	7.5	7.5	0.65	1	2	0.01	0.05

* The number of points used for computation of the prior(s) was 4.
‡ Power was calculated using M1 = E(M1) = 7.5, M2 = E(M2) = 7.5, COV = E(COV) = 0.65, δ = E(δ) = 1, σ = E(σ) = 2, and ρ = E(ρ) = 0.01.

This report shows the required sample size for each assurance target.

Plots Section

Plots



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

Example 4 – Joint Prior Distribution

Suppose a two-sided, two-sample t-test will be used in which K1 = K2 = (10, 20, 30) and the significance level is 0.05.

The joint prior distribution of the parameters is approximated by the following table. Note that the labels in parentheses identify the corresponding column of the spreadsheet. Also note that the prior probabilities in C7 will be automatically rescaled so that they sum to one.

δ (C1)	σ (C2)	ρ (C3)	M1 (C4)	M2 (C5)	COV (C6)	Prob (C7)
1.00	2.00	0.01	5	5	0.65	0.25
1.00	2.00	0.01	10	10	0.65	0.20
1.00	2.00	0.01	5	5	0.55	0.25
1.00	2.00	0.01	10	10	0.55	0.20
0.75	1.70	0.01	5	5	0.65	0.65
0.75	1.70	0.01	10	10	0.65	0.60
0.75	1.70	0.01	5	5	0.55	0.65
0.75	1.70	0.01	10	10	0.55	0.60
0.50	1.50	0.01	5	5	0.65	0.45
0.50	1.50	0.01	10	10	0.65	0.40
0.50	1.50	0.01	5	5	0.55	0.45
0.50	1.50	0.01	10	10	0.55	0.40
0.25	1.25	0.01	5	5	0.65	0.25
0.25	1.25	0.01	10	10	0.65	0.20
0.25	1.25	0.01	5	5	0.55	0.25
0.25	1.25	0.01	10	10	0.55	0.20
1.00	2.00	0.02	5	5	0.65	0.15
1.00	2.00	0.02	10	10	0.65	0.10
1.00	2.00	0.02	5	5	0.55	0.15
1.00	2.00	0.02	10	10	0.55	0.10
0.75	1.70	0.02	5	5	0.65	0.35
0.75	1.70	0.02	10	10	0.65	0.30
0.75	1.70	0.02	5	5	0.55	0.35
0.75	1.70	0.02	10	10	0.55	0.30
0.50	1.50	0.02	5	5	0.65	0.25
0.50	1.50	0.02	10	10	0.65	0.20
0.50	1.50	0.02	5	5	0.55	0.25
0.50	1.50	0.02	10	10	0.55	0.20
0.25	1.25	0.02	5	5	0.65	0.15
0.25	1.25	0.02	10	10	0.65	0.10
0.25	1.25	0.02	5	5	0.55	0.15
0.25	1.25	0.02	10	10	0.55	0.10

To run this example, the spreadsheet will need to be loaded with the above data.

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 .... **Assurance**
Prior Entry Method .... **Combined (Enter parameter values and probabilities on spreadsheet)**
Alternative Hypothesis .... **Two-Sided (H1: δ ≠ 0)**
Test Statistic .... **T-Test Based on Number of Subjects**
Alpha... **0.05**
K1 (Number of Clusters) **10 20 30**
Column of M1 Values..................................... **C4**
K2 (Number of Clusters) **K1**
Column of M2 Values..................................... **C5**
Column of COV Values.................................. **C6**
Column of δ Values **C1**
Column of σ Values **C2**
Column of ρ Values **C3**
Column of Pr(Values)..................................... **C7**

Options Tab

Number of Computation Points for each Prior Distribution **4**
Maximum K1 in Sample Size Search............. **1000**

Input Spreadsheet Data

Row	C1	C2	C3	C4	C5	C6	C7
1	1.00	2.00	0.01	5	5	0.65	0.25
2	1.00	2.00	0.01	10	10	0.65	0.20
3	1.00	2.00	0.01	5	5	0.55	0.25
4	1.00	2.00	0.01	10	10	0.55	0.20
5	0.75	1.70	0.01	5	5	0.65	0.65
6	0.75	1.70	0.01	10	10	0.65	0.60
7	0.75	1.70	0.01	5	5	0.55	0.65
8	0.75	1.70	0.01	10	10	0.55	0.60
9	0.50	1.50	0.01	5	5	0.65	0.45
10	0.50	1.50	0.01	10	10	0.65	0.40
11	0.50	1.50	0.01	5	5	0.55	0.45
12	0.50	1.50	0.01	10	10	0.55	0.40
13	0.25	1.25	0.01	5	5	0.65	0.25
14	0.25	1.25	0.01	10	10	0.65	0.20
15	0.25	1.25	0.01	5	5	0.55	0.25
16	0.25	1.25	0.01	10	10	0.55	0.20
17	1.00	2.00	0.02	5	5	0.65	0.15
18	1.00	2.00	0.02	10	10	0.65	0.10
19	1.00	2.00	0.02	5	5	0.55	0.15
20	1.00	2.00	0.02	10	10	0.55	0.10
21	0.75	1.70	0.02	5	5	0.65	0.35
22	0.75	1.70	0.02	10	10	0.65	0.30

23	0.75	1.70	0.02	5	5	0.55	0.35
24	0.75	1.70	0.02	10	10	0.55	0.30
25	0.50	1.50	0.02	5	5	0.65	0.25
26	0.50	1.50	0.02	10	10	0.65	0.20
27	0.50	1.50	0.02	5	5	0.55	0.25
28	0.50	1.50	0.02	10	10	0.55	0.20
29	0.25	1.25	0.02	5	5	0.65	0.15
30	0.25	1.25	0.02	10	10	0.65	0.10
31	0.25	1.25	0.02	5	5	0.55	0.15
32	0.25	1.25	0.02	10	10	0.55	0.10

Output

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

Numeric Results

Solve For: Assurance
Groups: 1 = Treatment, 2 = Control
Test Statistic: T-Test with DF based on number of subjects
Hypotheses: H0: δ = 0 vs. H1: δ ≠ 0
Prior Type: Joint Multivariate Distribution

Prior Distribution
Point Lists
M1: C4: 5 10 5 10 5 10 5 10 5 10 5 10 5 10 5 10 5 10 5 10 5 10 5 10 5 10 5 10 5 10 5 10
M2: C5: 5 10 5 10 5 10 5 10 5 10 5 10 5 10 5 10 5 10 5 10 5 10 5 10 5 10 5 10 5 10 5 10
COV: C6: 0.65 0.65 0.55 0.55 0.65 0.65 0.55 0.55 0.65 0.65 0.55 0.55 0.65 0.65 0.55 0.55 0.65 0.65 0.55 0.55 0.65 0.65 0.55 0.55 0.65 0.65 0.55 0.55 0.65 0.65 0.55 0.55
δ: C1: 1 1 1 1 0.75 0.75 0.75 0.75 0.5 0.5 0.5 0.5 0.25 0.25 0.25 0.25 1 1 1 1 0.75 0.75 0.75 0.75 0.5 0.5 0.5 0.5 0.25 0.25 0.25 0.25
σ: C2: 2 2 2 2 1.7 1.7 1.7 1.7 1.5 1.5 1.5 1.5 1.25 1.25 1.25 1.25 2 2 2 2 1.7 1.7 1.7 1.7 1.5 1.5 1.5 1.5 1.25 1.25 1.25 1.25
ρ: C3: 0.01 0.01 0.01 0.01 0.01 0.01 0.01 0.01 0.01 0.01 0.01 0.01 0.01 0.01 0.01 0.01 0.02 0.02 0.02 0.02 0.02 0.02 0.02 0.02 0.02 0.02 0.02 0.02 0.02 0.02 0.02 0.02
Prob: C7: 0.25 0.2 0.25 0.2 0.65 0.6 0.65 0.6 0.45 0.4 0.45 0.4 0.25 0.2 0.25 0.2 0.15 0.1 0.15 0.1 0.35 0.3 0.35 0.3 0.25 0.2 0.25 0.2 0.15 0.1 0.15 0.1

		Sample Size			Number of Clusters			Cluster Size			Mean Difference	Standard Deviation	Intracluster Correlation	
Assurance	Power‡	N1	N2	N	K1	K2	K	E(M1)	E(M2)	E(COV)	E(δ)	E(σ)	E(ρ)	Alpha
0.55958	0.61263	73	73	146	10	10	20	7.3	7.3	0.6	0.6413	1.62065	0.01348	0.05
0.78294	0.89014	146	146	292	20	20	40	7.3	7.3	0.6	0.6413	1.62065	0.01348	0.05
0.87441	0.97429	219	219	438	30	30	60	7.3	7.3	0.6	0.6413	1.62065	0.01348	0.05

‡ Power was calculated using M1 = E(M1) = 7.3, M2 = E(M2) = 7.3, COV = E(COV) = 0.6, δ = E(δ) = 0.6413, σ = E(σ) = 1.62065, and ρ = E(ρ) = 0.01348.

PASS has calculated the required number of clusters to achieve each assurance goal.

Example 5 – Joint Prior Distribution Validation

The problem given in Example 2 will be used to validate the joint prior distribution method. This will be done by running the individual-prior scenario used in that example through the joint-prior method and checking that the assurance values match.

In Example 2, the prior distribution of δ is given as follows.

δ	Prob
-0.3	0.4
0.7	0.6

The prior distribution of the σ is approximated by the following table.

σ	Prob
1.5	0.4
2.5	0.6

The prior distribution of the ρ is approximated by the following table.

ρ	Prob
0.01	0.5
0.02	0.5

The prior distribution of the M1 is approximated by the following table.

M1	Prob
7	0.5
9	0.5

The prior distribution of the M2 is approximated by the following table.

M2	Prob
7	0.5
9	0.5

The prior distribution of the COV is approximated by the following table.

COV	Prob
0.6	0.3
0.7	0.7

The joint prior distribution can be found by multiplying the independent probabilities. This results in the following discrete probability distribution.

M1 (C1)	M2 (C2)	COV(C3)	δ (C4)	σ (C5)	ρ (C6)	Prob (C7)
7	7	0.6	-0.3	1.5	0.01	0.006
7	7	0.7	-0.3	1.5	0.01	0.014
7	9	0.6	-0.3	1.5	0.01	0.006
7	9	0.7	-0.3	1.5	0.01	0.014
9	7	0.6	-0.3	1.5	0.01	0.006
9	7	0.7	-0.3	1.5	0.01	0.014
9	9	0.6	-0.3	1.5	0.01	0.006
9	9	0.7	-0.3	1.5	0.01	0.014
7	7	0.6	-0.3	1.5	0.02	0.006
7	7	0.7	-0.3	1.5	0.02	0.014

7	9	0.6	-0.3	1.5	0.02	0.006
7	9	0.7	-0.3	1.5	0.02	0.014
9	7	0.6	-0.3	1.5	0.02	0.006
9	7	0.7	-0.3	1.5	0.02	0.014
9	9	0.6	-0.3	1.5	0.02	0.006
9	9	0.7	-0.3	1.5	0.02	0.014
7	7	0.6	-0.3	2.5	0.01	0.009
7	7	0.7	-0.3	2.5	0.01	0.021
7	9	0.6	-0.3	2.5	0.01	0.009
7	9	0.7	-0.3	2.5	0.01	0.021
9	7	0.6	-0.3	2.5	0.01	0.009
9	7	0.7	-0.3	2.5	0.01	0.021
9	9	0.6	-0.3	2.5	0.01	0.009
9	9	0.7	-0.3	2.5	0.01	0.021
7	7	0.6	-0.3	2.5	0.02	0.009
7	7	0.7	-0.3	2.5	0.02	0.021
7	9	0.6	-0.3	2.5	0.02	0.009
7	9	0.7	-0.3	2.5	0.02	0.021
9	7	0.6	-0.3	2.5	0.02	0.009
9	7	0.7	-0.3	2.5	0.02	0.021
9	9	0.6	-0.3	2.5	0.02	0.009
9	9	0.7	-0.3	2.5	0.02	0.021
7	7	0.6	0.7	1.5	0.01	0.009
7	7	0.7	0.7	1.5	0.01	0.021
7	9	0.6	0.7	1.5	0.01	0.009
7	9	0.7	0.7	1.5	0.01	0.021
9	7	0.6	0.7	1.5	0.01	0.009
9	7	0.7	0.7	1.5	0.01	0.021
9	9	0.6	0.7	1.5	0.01	0.009
9	9	0.7	0.7	1.5	0.01	0.021
7	7	0.6	0.7	1.5	0.02	0.009
7	7	0.7	0.7	1.5	0.02	0.021
7	9	0.6	0.7	1.5	0.02	0.009
7	9	0.7	0.7	1.5	0.02	0.021
9	7	0.6	0.7	1.5	0.02	0.009
9	7	0.7	0.7	1.5	0.02	0.021
9	9	0.6	0.7	1.5	0.02	0.009
9	9	0.7	0.7	1.5	0.02	0.021
7	7	0.6	0.7	2.5	0.01	0.0135
7	7	0.7	0.7	2.5	0.01	0.0315
7	9	0.6	0.7	2.5	0.01	0.0135
7	9	0.7	0.7	2.5	0.01	0.0315
9	7	0.6	0.7	2.5	0.01	0.0135
9	7	0.7	0.7	2.5	0.01	0.0315
9	9	0.6	0.7	2.5	0.01	0.0135
9	9	0.7	0.7	2.5	0.01	0.0315
7	7	0.6	0.7	2.5	0.02	0.0135
7	7	0.7	0.7	2.5	0.02	0.0315
7	9	0.6	0.7	2.5	0.02	0.0135

7	**9**	**0.7**	**0.7**	**2.5**	**0.02**	**0.0315**
9	**7**	**0.6**	**0.7**	**2.5**	**0.02**	**0.0135**
9	**7**	**0.7**	**0.7**	**2.5**	**0.02**	**0.0315**
9	**9**	**0.6**	**0.7**	**2.5**	**0.02**	**0.0135**
9	**9**	**0.7**	**0.7**	**2.5**	**0.02**	**0.0315**

To run this example, the spreadsheet is loaded with the above data.

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 5** 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 .... **Assurance**
Prior Entry Method .... **Combined (Enter parameter values and probabilities on spreadsheet)**
Alternative Hypothesis .... **Two-Sided (H1: δ ≠ 0)**
Test Statistic .... **T-Test Based on Number of Subjects**
Alpha... **0.05**
K1 (Number of Clusters) **30**
Column of M1 Values.................................... **C1**
K2 (Number of Clusters) **K1**
Column of M2 Values.................................... **C2**
Column of COV Values.................................. **C3**
Column of δ Values **C4**
Column of σ Values **C5**
Column of ρ Values **C6**
Column of Pr(Values).................................... **C7**

Options Tab

Number of Computation Points for each Prior Distribution........ **4**
Maximum K1 in Sample Size Search............. **1000**

Input Spreadsheet Data

Row	C1	C2	C3	C4	C5	C6	C7
1	7	7	0.6	-0.3	1.5	0.01	0.0060
2	7	7	0.7	-0.3	1.5	0.01	0.0140
3	7	9	0.6	-0.3	1.5	0.01	0.0060
4	7	9	0.7	-0.3	1.5	0.01	0.0140
5	9	7	0.6	-0.3	1.5	0.01	0.0060
6	9	7	0.7	-0.3	1.5	0.01	0.0140
7	9	9	0.6	-0.3	1.5	0.01	0.0060
8	9	9	0.7	-0.3	1.5	0.01	0.0140
9	7	7	0.6	-0.3	1.5	0.02	0.0060
10	7	7	0.7	-0.3	1.5	0.02	0.0140
11	7	9	0.6	-0.3	1.5	0.02	0.0060
12	7	9	0.7	-0.3	1.5	0.02	0.0140

13	9	7	0.6	-0.3	1.5	0.02	0.0060
14	9	7	0.7	-0.3	1.5	0.02	0.0140
15	9	9	0.6	-0.3	1.5	0.02	0.0060
16	9	9	0.7	-0.3	1.5	0.02	0.0140
17	7	7	0.6	-0.3	2.5	0.01	0.0090
18	7	7	0.7	-0.3	2.5	0.01	0.0210
19	7	9	0.6	-0.3	2.5	0.01	0.0090
20	7	9	0.7	-0.3	2.5	0.01	0.0210
21	9	7	0.6	-0.3	2.5	0.01	0.0090
22	9	7	0.7	-0.3	2.5	0.01	0.0210
23	9	9	0.6	-0.3	2.5	0.01	0.0090
24	9	9	0.7	-0.3	2.5	0.01	0.0210
25	7	7	0.6	-0.3	2.5	0.02	0.0090
26	7	7	0.7	-0.3	2.5	0.02	0.0210
27	7	9	0.6	-0.3	2.5	0.02	0.0090
28	7	9	0.7	-0.3	2.5	0.02	0.0210
29	9	7	0.6	-0.3	2.5	0.02	0.0090
30	9	7	0.7	-0.3	2.5	0.02	0.0210
31	9	9	0.6	-0.3	2.5	0.02	0.0090
32	9	9	0.7	-0.3	2.5	0.02	0.0210
33	7	7	0.6	0.7	1.5	0.01	0.0090
34	7	7	0.7	0.7	1.5	0.01	0.0210
35	7	9	0.6	0.7	1.5	0.01	0.0090
36	7	9	0.7	0.7	1.5	0.01	0.0210
37	9	7	0.6	0.7	1.5	0.01	0.0090
38	9	7	0.7	0.7	1.5	0.01	0.0210
39	9	9	0.6	0.7	1.5	0.01	0.0090
40	9	9	0.7	0.7	1.5	0.01	0.0210
41	7	7	0.6	0.7	1.5	0.02	0.0090
42	7	7	0.7	0.7	1.5	0.02	0.0210
43	7	9	0.6	0.7	1.5	0.02	0.0090
44	7	9	0.7	0.7	1.5	0.02	0.0210
45	9	7	0.6	0.7	1.5	0.02	0.0090
46	9	7	0.7	0.7	1.5	0.02	0.0210
47	9	9	0.6	0.7	1.5	0.02	0.0090
48	9	9	0.7	0.7	1.5	0.02	0.0210
49	7	7	0.6	0.7	2.5	0.01	0.0135
50	7	7	0.7	0.7	2.5	0.01	0.0315
51	7	9	0.6	0.7	2.5	0.01	0.0135
52	7	9	0.7	0.7	2.5	0.01	0.0315
53	9	7	0.6	0.7	2.5	0.01	0.0135
54	9	7	0.7	0.7	2.5	0.01	0.0315
55	9	9	0.6	0.7	2.5	0.01	0.0135
56	9	9	0.7	0.7	2.5	0.01	0.0315
57	7	7	0.6	0.7	2.5	0.02	0.0135
58	7	7	0.7	0.7	2.5	0.02	0.0315
59	7	9	0.6	0.7	2.5	0.02	0.0135
60	7	9	0.7	0.7	2.5	0.02	0.0315
61	9	7	0.6	0.7	2.5	0.02	0.0135
62	9	7	0.7	0.7	2.5	0.02	0.0315
63	9	9	0.6	0.7	2.5	0.02	0.0135
64	9	9	0.7	0.7	2.5	0.02	0.0315

Output

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

Numeric Results

Solve For: Assurance
Groups: 1 = Treatment, 2 = Control
Test Statistic: T-Test with DF based on number of subjects
Hypotheses: H0: δ = 0 vs. H1: δ ≠ 0
Prior Type: Joint Multivariate Distribution

Prior Distribution
Point Lists
M1: C1: 7 7 7 7 9 9 9 9 7 7 7 7 9 9 9 9 7 7 7 7 9 9 9 9 7 7 7 7 9 9 9 9 7 7 7 7 9 9 9 9 7 7 7 7 9 9 9 9 7 7 7 7 9 9 9 9 7 7 7 7 9 9 9 9
M2: C2: 7 7 9 9 7 7 9 9 7 7 9 9 7 7 9 9 7 7 9 9 7 7 9 9 7 7 9 9 7 7 9 9 7 7 9 9 7 7 9 9 7 7 9 9 7 7 9 9 7 7 9 9 7 7 9 9 7 7 9 9 7 7 9 9
COV: C3: 0.6 0.7
δ: C4: -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 -0.3 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7
σ: C5: 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 1.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5 2.5
ρ: C6: 0.01 0.01 0.01 0.01 0.01 0.01 0.01 0.01 0.02 0.02 0.02 0.02 0.02 0.02 0.02 0.02 0.01 0.01 0.01 0.01 0.01 0.01 0.01 0.01 0.02 0.02 0.02 0.02 0.02 0.02 0.02 0.02 0.01 0.01 0.01 0.01 0.01 0.01 0.01 0.01 0.02 0.02 0.02 0.02 0.02 0.02 0.02 0.02 0.01 0.01 0.01 0.01 0.01 0.01 0.01 0.01 0.02 0.02 0.02 0.02 0.02 0.02 0.02 0.02
Prob: C7: 0.006 0.014 0.006 0.014 0.006 0.014 0.006 0.014 0.006 0.014 0.006 0.014 0.006 0.014 0.006 0.014 0.009 0.021 0.009 0.021 0.009 0.021 0.009 0.021 0.009 0.021 0.009 0.021 0.009 0.021 0.009 0.021 0.009 0.021 0.009 0.021 0.009 0.021 0.009 0.021 0.009 0.021 0.009 0.021 0.009 0.021 0.009 0.021 0.0135 0.0315 0.0135 0.0315 0.0135 0.0315 0.0135 0.0315 0.0135 0.0315 0.0135 0.0315 0.0135 0.0315 0.0135 0.0315

		Sample Size			Number of Clusters			Cluster Size			Mean Difference	Standard Deviation	Intracluster Correlation	
Assurance	Power‡	N1	N2	N	K1	K2	K	E(M1)	E(M2)	E(COV)	E(δ)	E(σ)	E(ρ)	Alpha
0.6694	0.3075	241	241	482	30	30	60	8	8	0.67	0.3	2.1	0.015	0.05

‡ Power was calculated using M1 = E(M1) = 8, M2 = E(M2) = 8, COV = E(COV) = 0.67, δ = E(δ) = 0.3, σ = E(σ) = 2.1, and ρ = E(ρ) = 0.015.

PASS has calculated the assurance as 0.6694 which matches the result in Example 2. This validates the joint prior method.