

## Chapter 828

# Confidence Intervals for Intraclass Correlation with Assurance Probability (Lower One-Sided)

## Introduction

This routine calculates the sample size needed to obtain a specified width of a lower one-sided confidence interval of the intraclass correlation coefficient (ICC). This procedure allows you to set an *assurance probability* that the requested width is achieved. Note that another **PASS** procedure computes the sample size for a two-sided confidence interval for the ICC.

The ICC is the product-moment correlation calculated among observations on the same subject. For example, if you have three raters rating each subject, it is the average correlation among the ratings of the three raters. This procedure is often used in reliability studies.

The ICC analyzed in this procedure comes from a one-way random effects ANOVA model.

## Technical Details

Zou (2012) presents formulas used for constructing a lower one-sided,  $100(1 - \alpha)\%$  confidence interval for the ICC. We adopt his notation as we present these formulas.

Suppose that each of  $N$  subjects (or clusters) is rated by  $K$  raters. The observations obtained may be from different raters, instruments, or other measurement mechanisms. Such data may be analyzed using a one-way, random-effects, model. The ANOVA model is

$$Y_{ij} = \mu + \alpha_i + \varepsilon_{ij} \text{ where } \alpha_i \sim N(0, \sigma_\alpha^2) \text{ and } \varepsilon_{ij} \sim N(0, \sigma_\varepsilon^2).$$

## Estimation of $\rho$

The ICC is defined as

$$\rho = \frac{\sigma_\alpha^2}{\sigma_\alpha^2 + \sigma_\varepsilon^2}$$

The ICC is estimated from the mean squares of the ANOVA table as follows

$$r = \frac{MS_B - MS_E}{MS_B + (K - 1)MS_E}$$

where  $MS_B$  is the between-subject mean square and  $MS_E$  is the within-subject mean square.

## Confidence Intervals for Intraclass Correlation with Assurance Probability (Lower One-Sided)

Confidence limits  $r_L$  and  $r_U$  for  $\rho$  are obtained using the formulas

$$r_L = \frac{F_L - 1}{F_L + K - 1}, \quad r_U = \frac{F_U - 1}{F_U + K - 1}$$

where

$$F_L = \frac{F_O}{F_{1-\alpha/2, V2, V1}}, \quad F_U = F_O F_{1-\alpha/2, V1, V2}, \quad F_O = \frac{MS_B}{MS_E}, \quad V1 = N(K - 1), \quad V2 = N - 1.$$

One-sided bounds may be obtained by replacing  $\alpha/2$  by  $\alpha$ .

This procedure will only provide results for lower one-sided confidence intervals.

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## Sample Size Calculation

The procedure focuses on the case where the main concern is that the reliability coefficient,  $\rho$ , is not less than a prespecified value,  $\rho_0$ . Thus, the primary objective of the study is to determine if the ICC is of acceptable magnitude. Landis and Koch (1977) provide the following guidelines which are often used when select an appropriate value of  $\rho_0$ .

<b>ICC Range</b>	<b>Definition</b>
$\rho < 0$	Poor
$0.0 \leq \rho < 0.2$	Slight
$0.2 \leq \rho < 0.4$	Fair
$0.4 \leq \rho < 0.6$	Moderate
$0.6 \leq \rho < 0.8$	Substantial
$0.8 \leq \rho < 1.0$	Almost Perfect

For example, if one wants a 'substantial' value, they should select  $\rho_0 = 0.6$ .

The sample size is determined so that the probability that the requested limit is achieved is above a specified value. This probability is called the *assurance probability* and is referred to as  $1 - \gamma$ .

The assurance probability requirement is written as

$$1 - \gamma = \Pr(\rho_L \geq \rho_0)$$

It turns out that this formulation may also be used to obtain the power of the corresponding hypothesis test.

## Confidence Intervals for Intraclass Correlation with Assurance Probability (Lower One-Sided)

Donner and Eliasziw (1987) showed that if the one-way model normality assumptions are met, the *assurance probability* could be calculated exactly using the F distribution as follows

$$1 - \gamma = \Pr(F \geq C_0 F_{\alpha, v1, v2})$$

where

$$v1 = N - 1$$

$$v2 = N(K - 1)$$

$$C_0 = \frac{1 + K\theta_0}{1 + K\theta_1}$$

$$\theta_0 = \frac{\rho_0}{1 - \rho_0}$$

$$\theta_1 = \frac{\rho_1}{1 - \rho_1}$$

Here,  $\rho_1$  is used to represent the true value of  $\rho$ . Care must be taken so that  $\rho_0 < \rho_1$ .

Zou (2012) presented a close approximation to the assurance probability based on Fisher's transformation which could be solved directly for sample size. The resulting equation is

$$N = 1 + \frac{2K(z_\alpha + z_\gamma)^2}{\left\{ \ln \left[ \frac{F(\rho_1)}{F(\rho_0)} \right] \right\}^2 (K - 1)}$$

where

$$F(\rho) = \frac{1 + (K - 1)\rho}{1 - \rho}$$

This can be rearranged to solve for the assurance probability or  $\rho_0$  as well.

In **PASS**, you can choose to use the exact calculation based of the F distribution or the approximate solution based on Fisher's transformation.

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## Confidence Level

The confidence level,  $1 - \alpha$ , has the following interpretation. If thousands of samples of  $n$  items are drawn from a population using simple random sampling and a confidence interval is calculated for each sample, the proportion of those intervals that will include the true population correlation is  $1 - \alpha$ .

## Example 1 – Calculating Sample Size

Suppose a reliability study is planned to find an estimate of the lower one-sided 95% confidence interval for the ICC. The researcher would like to examine values of  $K$  from 2 to 10. The goal is to determine the necessary sample size,  $N$ , when the assurance probability is 0.9, the lower confidence bound of  $p$  is 0.5, and the lower confidence bound is 0.6.

### 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 .....	<b>Number of Subjects (N)</b>
Calculation Method .....	<b>Exact F Distribution</b>
Confidence Level ( $1 - \alpha$ ) .....	<b>0.95</b>
$1 - \gamma$ (Assurance Probability) .....	<b>0.9</b>
$K$ (Observations per Subject) .....	<b>2 4 6 8 10</b>
$p_0$ (Lower Confidence Bound of $p$ ) .....	<b>0.5</b>
$p_1$ (True Value of $p$ ) .....	<b>0.6</b>

## Confidence Intervals for Intraclass Correlation with Assurance Probability (Lower One-Sided)

## Output

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

## Numeric Reports

### Numeric Results

Solve For: **Number of Subjects (N)**  
 Confidence Interval: Lower, One-Sided  
 Calculation Method: Exact, Based on F Distribution

Confidence Level 1 - $\alpha$	Number of Subjects N	Observations per Subject K	Intraclass Correlation Coefficient			Assurance Probability	
			Lower Confidence Bound $\rho_0$	True Value $\rho_1$	Distance from $\rho_1$ to $\rho_0$	Target 1 - $\gamma_T$	Actual 1 - $\gamma_A$
0.95	416	2	0.5	0.6	0.1	0.9	0.90045
0.95	202	4	0.5	0.6	0.1	0.9	0.90030
0.95	162	6	0.5	0.6	0.1	0.9	0.90074
0.95	145	8	0.5	0.6	0.1	0.9	0.90049
0.95	136	10	0.5	0.6	0.1	0.9	0.90089

Confidence Level	The proportion of confidence intervals (constructed with this same confidence level, sample size, etc.) that would contain the true correlation.
N	The number of subjects in the random sample drawn from the population.
K	The number of observations obtained for each subject.
$\rho_0$	The lower confidence limit of the intraclass correlation coefficient ( $\rho$ ).
$\rho_1$	The true value of the intraclass correlation coefficient ( $\rho$ ).
$\rho_1 - \rho_0$	The distance from $\rho_1$ to $\rho_0$ . It is a measure of the half-width of the confidence interval. Since the confidence limits are not symmetric, this is not the exact half-width.
1 - $\gamma_T$	The target assurance probability that the confidence interval will include the true value of $\rho$ .
1 - $\gamma_A$	The actual assurance probability that is achieved for this sample size.

### Summary Statements

A single-group design, with each subject measured 2 times, will be used to obtain a one-sided lower limit 95% confidence interval for a single intraclass correlation coefficient. It is assumed that the data will be analyzed using a one-way ANOVA model. The assurance probability will be calculated using the exact method of Donner and Eliasziw (1987), based on the F distribution. The true intraclass correlation coefficient is assumed to be 0.6. To produce a confidence interval with 0.9 probability that the lower limit confidence bound will be no less than 0.5, 416 subjects will be needed.

## Confidence Intervals for Intraclass Correlation with Assurance Probability (Lower One-Sided)

**Dropout-Inflated Sample Size**

Dropout Rate	Sample Size N	Dropout- Inflated Enrollment Sample Size N'	Expected Number of Dropouts D
20%	416	520	104
20%	202	253	51
20%	162	203	41
20%	145	182	37
20%	136	170	34

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

**Dropout Summary Statements**

Anticipating a 20% dropout rate, 520 subjects should be enrolled to obtain a final sample size of 416 subjects.

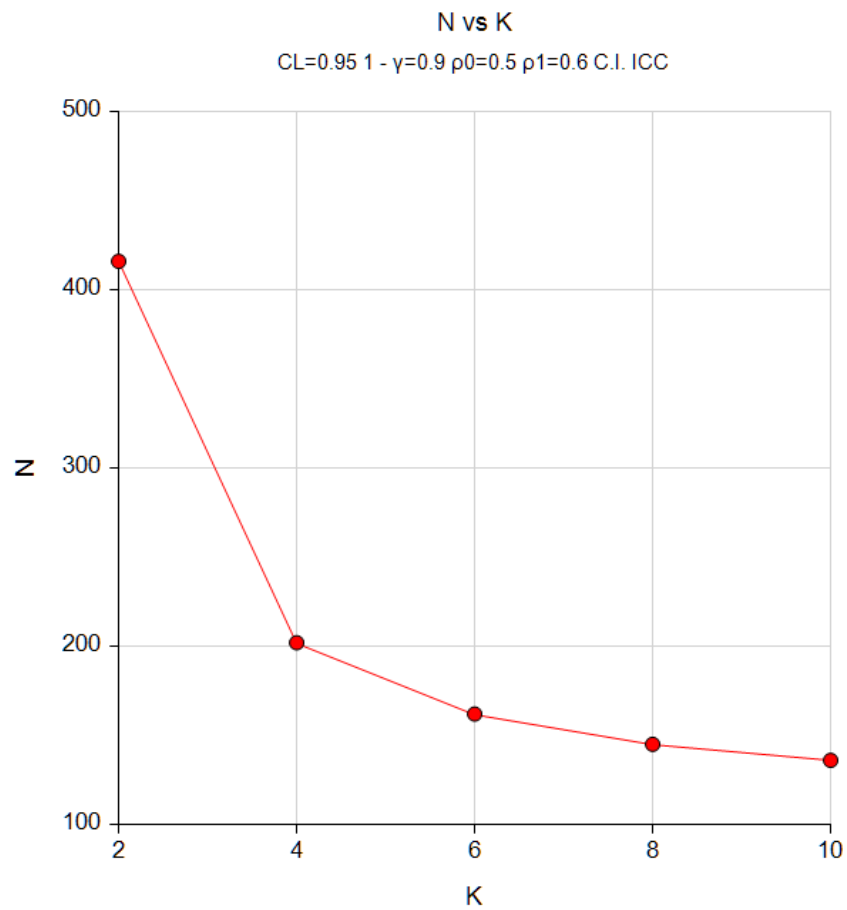
**References**

- Zou, G.Y. 2012. 'Sample size formulas for estimating intraclass correlation coefficients with precision and assurance.' *Statistics in Medicine*, Vol 31, 3972-3981.
- Donner, A, Eliasziw, M. 1987. 'Sample size requirements for reliability studies.' *Statistics in Medicine*, Vol 6, 441-448.
- Bartko, John J. 1966. 'The intraclass correlation coefficient as a measure of reliability.' *Psychological Reports*, Vol 19, 3-11.

This report shows the calculated sample size for each of the scenarios.

## Plots Section

### Plots



This plot shows the sample size versus the value of K.

## Example 2 – Validation using Zou (2012)

Zou (2012), page 3978, gives example calculations of the number of subjects needed for a one-sided confidence interval of ICC when the confidence level is 95%,  $\rho_1$  is 0.60,  $\rho_0$  is 0.50, and  $K$  is 2. The result for  $N$  is 300 using the Fisher's transformation method.

### 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 ..... **Number of Subjects (N)**  
 Calculation Method ..... **Approximate Fisher Transformation**  
 Confidence Level ( $1 - \alpha$ ) ..... **0.95**  
 $1 - \gamma$  (Assurance Probability) ..... **0.8**  
 $K$  (Observations per Subject) ..... **2**  
 $\rho_0$  (Lower Confidence Bound of  $\rho$ ) ..... **0.5**  
 $\rho_1$  (True Value of  $\rho$ ) ..... **0.6**

### Output

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

#### Numeric Results

Solve For: [Number of Subjects \(N\)](#)  
 Confidence Interval: Lower, One-Sided  
 Calculation Method: Approximate, Based on Fisher's Transformation

Confidence Level $1 - \alpha$	Number of Subjects $N$	Observations per Subject $K$	Intraclass Correlation Coefficient			Assurance Probability	
			Lower Confidence Bound $\rho_0$	True Value $\rho_1$	Distance from $\rho_1$ to $\rho_0$ $\rho_1 - \rho_0$	Target $1 - \gamma_T$	Actual $1 - \gamma_A$
0.95	300	2	0.5	0.6	0.1	0.8	0.80022

**PASS** matches Zou's results exactly. We set the Calculation Method to Exact F Distribution and reran the procedure. This time,  $N$  was calculated to be 301. We note that in this case, the results of both methods are very close to each other.