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Sample Size Calculation Guide - Part 7: How to Calculate the Sample Size Based on a Correlation

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Introduction

In the previous educational articles, we explained how to calculate the sample size for a rate or a single proportion, for an independent cohort study, for an independent case-control study, for a diagnostic test accuracy study, for a superiority clinical trial, and for a non-inferiority or equivalence clinical trial (1-6). In this article, we will explain how to calculate the sample size for a clinical study with the aim of detecting the correlation coefficient between two variables.

When to use the sample size calculation procedure of a correlation

The methods explained hereafter should be used in case of a clinical study designed to determine the correlation between two variables. This study might be a cross-sectional study, a cohort study, a case-control study, or a clinical trial as long as the primary objective is to determine the correlation between two variables.

Requirements

1) Expected correlation coefficient
2) Statistical power
3) Alpha
4) Correlation coefficient for the null hypothesis (usually 0 or 0.2)

Calculation steps on StatsDirect Software

1) Open a new report
2) From "analysis" menu, select "sample size."
3) Then select "correlation."
4) Then submit the data

Calculation steps on the Statistics and Sample Size calculation Android app (Figure 1)

1) Open the app
2) Select "sample size calculator"

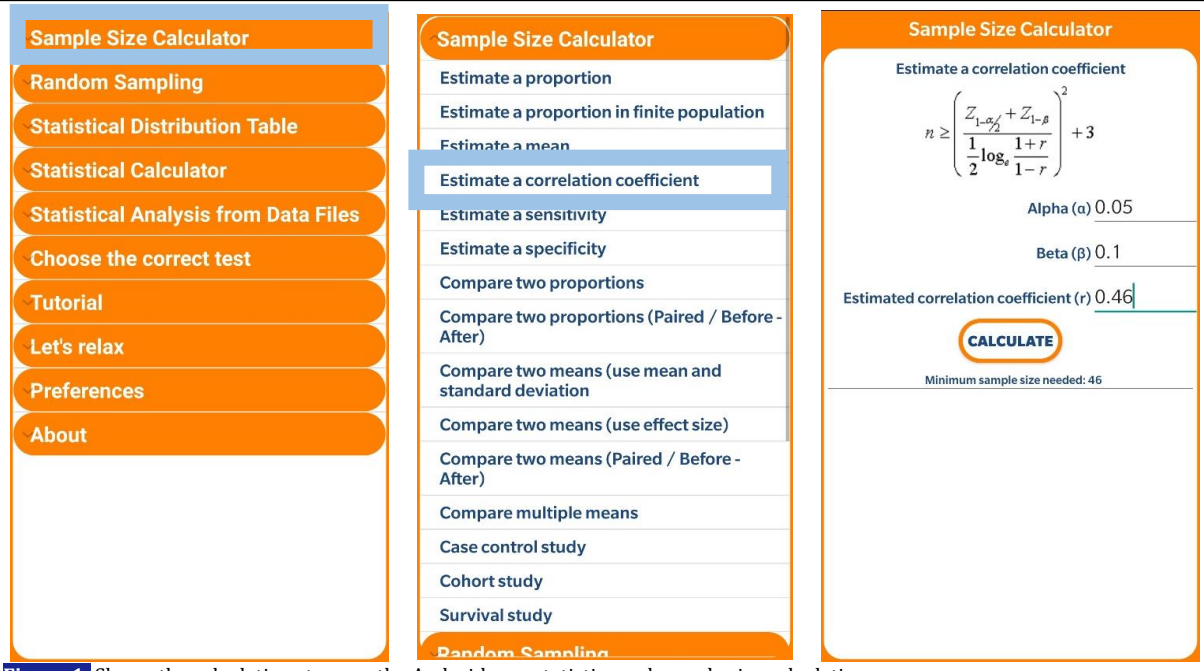

Figure 1: Shows the calculation steps on the Android app, statistics and sample size calculation

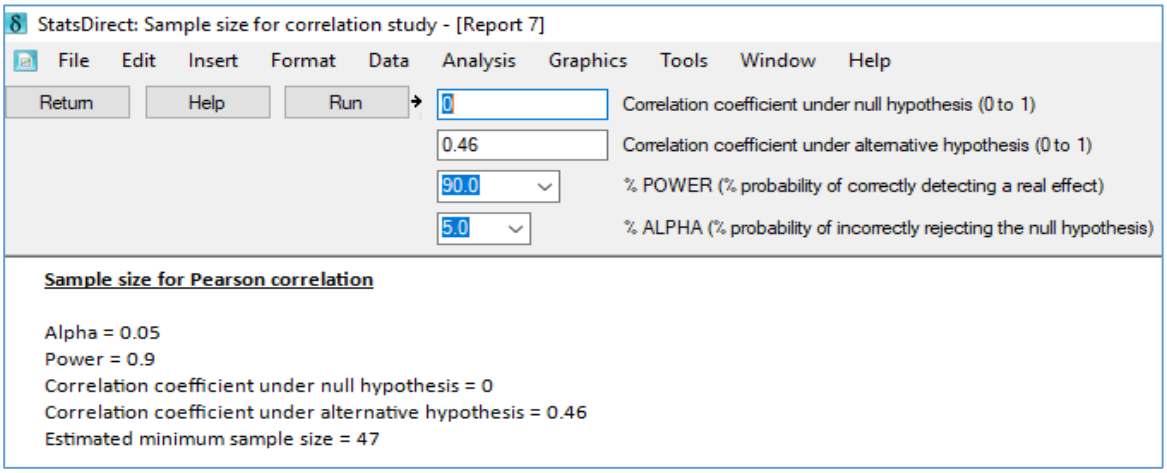

Figure 2: Shows the calculation steps on the StatsDirect software

3) Select "estimate the correlation coefficient"
4) Then submit the data

Case study of microRNA plasma levels as biomarkers for early detection of prostate cancer

Assume that we are conducting a study to investigate the role of microRNAs in plasma as potential biomarkers for early detection of prostate cancer (defined as elevated PSA). A recent study by McDonald et al. (7) reported the following sentence: "moderate positive correlations with serum PSA were observed for … miR-34a among cases (r = 0.46; P-value = 0.02)". The null hypothesis is that there is no correlation between microRNAs in the plasma and serum PSA (r=0). The alternative hypothesis based on McDonald et al. is that there is a moderate correlation between microRNAs in the plasma and serum PSA (r=0.46).

Case solution

First, we determine the requirements

- Expected correlation between the two variables (r=0.46)
- Statistical power = 90% (or Beta error=0.1)
- Alpha = 5%
- Correlation coefficient of the null hypothesis (r=0.0)

Second, we run the calculations using the Statistics and Sample Size calculation app on Android (Figure 1) or the StatsDirect software for windows (Figure 2). The results show that a minimum sample size of 47 patients will be required for this study.

Second, we run the calculations as shown in Figure 1. The results show that a minimum sample size of 156 patients (n=78 per group) will be required for this randomized controlled trial (Figure 1).

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