Sample Size Calculation Guide - Part 3: How to Calculate the Sample Size for an Independent Case-control Study

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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 and how to calculate the sample size for an independent cohort study (1, 2). In this article, we will explain how to calculate the sample size for an independent case-control study based on the odds ratios or two proportions representing the exposure rates in the case and the control groups.

WHEN TO USE THE SAMPLE SIZE CALCULATION PROCEDURE OF TWO PROPORTIONS

The methods explained hereafter should be used in the case that the primary outcome of your research study is expressed as odds ratio (OR) or two proportions. Although ORs are mainly obtained from case-control studies, other research designs might follow the same scenario if the primary outcome is a comparison of two proportions that will be represented as OR. Some prospective clinical trials report ORs to describe rare events. For example, a retrospective case-control study to evaluate the association between occupational lead exposure and kidney cancer. In this study, two groups of kidney cancer (cases) and healthy individuals (controls) are compared in terms of their history of occupational exposure to lead; the odds of lead exposure between in the two groups are expressed as OR.

REQUIREMENTS FOR SAMPLE SIZE CALCULATION BASED ON OR OR TWO PROPORTIONS FOR A CASE-CONTROL STUDY

(1) Expected OR: between exposed and non-exposed groups*
(2) The probability of exposure in cases*
(3) The probability of exposure in controls
(4) Statistical power: 0.8, 0.85, or 0.9

(5) Alpha: usually 0.05
(6) Number of controls per subject in the cases group (1 in case of equal groups)
* Either the OR or the probability of exposures in the cases will be needed.

EXAMPLE: A CASE-CONTROL STUDY ABOUT THE ASSOCIATION BETWEEN HCV INFECTION AND ORAL LICHEN PLANUS

Assume that we will conduct a case-control study to investigate the association between HCV infection and Oral Lichen Planus (OLP). Therefore, we will identify two groups from the population (cases: patients with OLP and control group: subjects without OLP).

A previous study by Manomaivat et al. showed that the odds ratio of association between exposure to HCV infection and developing OLP was 9.7 with a 1/101 prevalence rate of HCV among the control group (healthy population) (3).

The following steps will show how to calculate the sample size for a case-control study in order to detect a similar odds ratio with 90% statistical power and a 5% margin of error.

Calculations will be done by the Epi Info, a program developed by the Centers for Disease Control and Prevention available via the link: https://www.cdc.gov/epiinfo/index.html

First, open the software then select "STATCALC" for sample size calculation options (Figure 1). Then, select "unmatched case-control studies" (Figure 2). Finally, submit the data and check the table for the calculation results. As shown in Figure 3, the results table shows a sample size of 362 participants corresponding with a 95% confidence level. Therefore, the sample size calculation required for this study will be 362 patients (181 patients per group).

Figure 1: Epi Info main menu   **Figure 2:** STATCALC menu   **Figure 3:** Calculated result
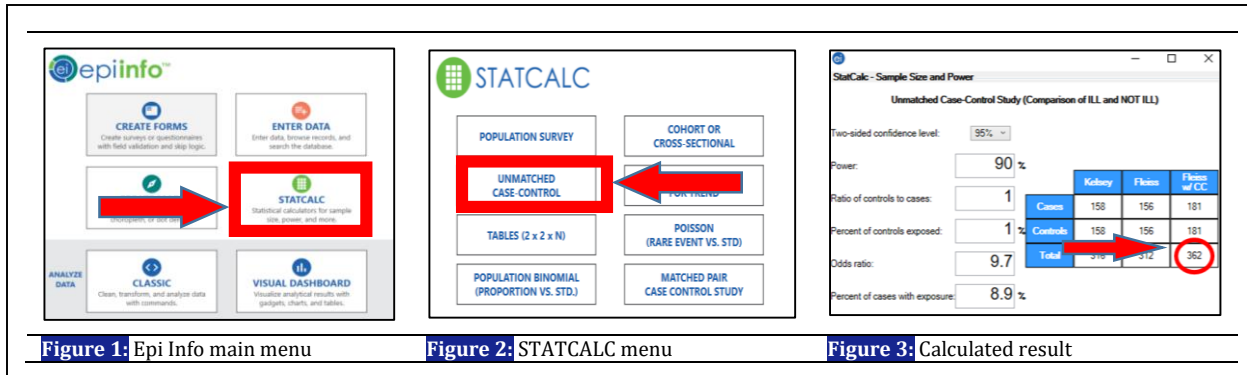
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