Open lecture on statistics

ISSN 2234-7658 (print) / ISSN 2234-7666 (online) http://dx.doi.org/10.5395/rde.2016.41.2.154



Statistical notes for clinical researchers: Sample size calculation 2. Comparison of two independent proportions

Hae-Young Kim*

Department of Health Policy and Management, College of Health Science, and Department of Public Health Sciences, Graduate School, Korea University, Seoul, Korea Principles and methods of sample size determination for the comparison of two independent means were introduced in the previous article.¹ In this article we will discuss sample size determination for the comparison of two independent proportions. While the same principles about power, α error, and β error can be applied as well, the selection of an adequate test is needed for the comparison of two independent proportions, depending on the condition whether the sample size is large enough or not.

Selection of two-sample test for proportions

The comparison of two independent proportions occurs when we perform an experiment with a binary outcome (e.g., success or failure) obtained from two groups (e.g., control vs. experiment groups). Let's call the sample sizes and proportions of success in the control and experimental groups as n_1 , n_2 , p_1 , and p_2 , respectively. When the sample size of an experiment is large enough (e.g., $n_1p_1 > 5$, and $n_2p_2 > 5$), we can assume the sampling distribution of proportions as approximately normal based on the central limit theorem. Therefore, when sample size is large enough, we can apply z test approximation in comparing two independent proportions and the same principle can be applied in the required sample size calculation.

The comparison of two proportions can be expressed as a 2×2 contingency table. When we test the association of two binary variables (two groups and two outcomes), we usually apply the Pearson chi-square test. When the sample size is large enough, the result of chi-square test and z test approximation are equally reliable and show the same result with an identical p value. If the condition satisfies for the application of the Pearson chi-square test, use of z test approximation in sample size calculation is justified.

However, if there is one or more cells with expected frequencies smaller than 5, statistical packages display the warning message that the Pearson chi-square test results cannot be reliable. In those cases, we need to apply the Fisher's exact test instead of the Pearson chi-square test. The Fisher's exact test is applicable when the sample size is small and we could expect that there may be one or more small cells (< 5). Therefore, different sample size calculation procedure following the Fisher's exact test will be applied when the sample size is small.

Calculation of sample size

1. Z test approximation for large sample test

When we suppose the sample size is large enough, following sample size calculation procedure can be performed based on z test approximation. Let's assume the following conditions: proportion of control group $(p_1) = 0.2$, proportion of experimental group $(p_2) = 0.3$. If we set α error level (two-sided) = 0.05 (corresponding $z_{\alpha/2} = 1.96$), power

This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (http://creativecommons.org/licenses/ by-nc/3.0) which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

Hae-Young Kim, DDS, PhD. Associate Professor, Depart

*Correspondence to

Associate Professor, Department of Health Policy and Management, College of Health Science, and Department of Public Health Sciences, Graduate School, Korea University, 145 Anam-ro, Seongbukgu, Seoul, Korea 02841 TEL, +82-2-3290-5667; FAX, +82-2-940-2879; E-mail, kimhaey@korea. ac.kr level = 0.8 (corresponding z_{β} = 0.84), and allocation ratio ($n_1 / n_2 = \kappa$) = 1, the sample size is calculated as approximately 291 subjects per group using the following formula.²

 $n_1 = \kappa n_2$, (when $\kappa = 1$, equal sample size assumed)

$$n_{2} = \frac{\left(Z_{\alpha/2} + Z_{\beta}\right)^{2}}{\left(p_{1} - p_{2}\right)^{2}} \left[\frac{\left(p_{1}(1 - p_{1}) + p_{2}(1 - p_{2})\right)^{2}}{\kappa} + p_{2}(1 - p_{2})\right]^{2} = \frac{\left(1.96 + 0.84\right)^{2}}{\left(0.2 - 0.3\right)^{2}} \left(0.2 \times 0.8 + 0.3 \times 0.7\right) = 290.08$$

The calculation procedure can be accomplished using the software G*Power. G*Power displays a similar result of sample size, 294 (Example 1).

2. Fisher's exact test for small samples test

When we expect the sample size is small and there may be one or more small cells (< 5), following sample size calculation procedure can be performed based on the Fisher's exact test. Let's assume the following conditions: proportion of control group $(p_1) = 0.05$, and proportion of experimental group $(p_2) = 0.3$. We set α error level (two-sided) = 0.05 (corresponding $z_{\alpha/2} = 1.96$), power level = 0.8 (corresponding $z_{\beta} = 0.84$), and allocation ratio $(n_1/n_2 = \kappa) = 1$. Because there is no definite formula related to the case, we need to use a software for sample size determination. Table 1 shows exemplary results applying various levels of proportions, α error, and power.

		$\alpha = 0.05$		$\alpha = 0.01$	
p_1	p_2	Power = 0.8	Power = 0.9	Power = 0.8	Power = 0.9
0.05	0.30	39	51	56	68
	0.40	24	31	35	42
	0.50	17	21	23	28
0.10	0.30	69	89	98	123
	0.40	36	47	51	64
	0.50	23	29	33	40

Table 1. Results of sample size determination for Fisher's exact test (two-sided)

Sample size determination procedure using G*Power

An appropriate sample size for the comparison of proportions can be obtained by performing the following steps using G*Power, a free software.

1. Z test approximation for two independent proportions (Large sample test)

Step 1: Select statistical test types

Menu: Tests - Proportions - Two Independent Groups: Inequality, z-Test

βά	G*Powe	1.9.2 – 🗆 🗙		
File Edit View	Tests Calculator Help Correlation and regression Means	lyses		
	Proportions Variances	One group: Difference From Constant One group: Sign Test		
	Generic	Two dependent groups: Inequality, McNemar test Two independent groups: Inequality, Fisher's exact test Two independent groups: Inequality, unconditional exact		
		Two independent groups: Inequality with offset, uncondit Two independent groups: Inequality, z-Test Multigroup: Goodness-of-Fit	ional exact	

```
Step 2: Select one-sided or two-sided test
Step 3: Select \alpha error level
Step 4: Select power level
Step 5: Select allocation ratio
Step 6: Calculation of sample size
Menu: Calculate
Example 1) Two tailed test
                                                                                             Test family
                                                                                                            Statistical test
                                                                                             z tests
                                                                                                           Proportions: Difference between two independent proportions
                                                                                                                                                                          v
                                                                                                      V
                 Proportions: p_1 = 0.2, p_2 = 0.3
                                                                                             Type of power analysis
                 \alpha error level = 0.05
                                                                                             A priori: Compute required sample size – given \boldsymbol{\alpha}, power, and effect size
                                                                                                                                                                          v
                 Power = 0.8
                                                                                             Input Parameters
                                                                                                                                     Output Parameters
                 Allocation ratio: n_1 / n_2 = 1
                                                                                                                Tail(s) Two V
                                                                                                                                                   Critical z
                                                                                                                                                                  -1.9599640
                 Appropriate sample size calculated: n_1 = n_2 = 294
                                                                                                                               0.2
                                                                                                           Proportion p2
                                                                                                                                           Sample size group 1
                                                                                                                                                                        294
                                                                                                                               0.3
                                                                                                                                                                        294
                                                                                                           Proportion p1
                                                                                                                                           Sample size group 2
                                                                                                                               0.05
                                                                                                                                                                        588
                                                                                                              \alpha \, err \, prob
                                                                                                                                              Total sample size
                                                                                                       Power (1-β err prob)
                                                                                                                               0.8
                                                                                                                                                 Actual power
                                                                                                                                                                  0.8011388
                                                                                                      Allocation ratio N2/N1
                                                                                                                                 1
                                                                                                                        Options
                                                                                                                                     X-Y plot for a range of values
                                                                                                                                                                 Calculate
```

2. Fisher exact test for two independent proportions (Small sample test)

Step 1: Select statistical test types
Menu: Tests - Proportions - Two Independent Groups: Inequality, Fisher's exact test
Step 2 - Step 5 (the same as example 1)
Step 6: Calculation of sample size
Menu: Calculate

Example 2)	Two tailed test Proportions: $p_1 = 0.05$, $p_2 = 0.30$ α error level = 0.05 Power = 0.8 Allocation ratio $n_1 / n_2 = 1$ Appropriate sample size calculated: $n_1 = n_2 = 39$	Test family Statistical test Exact v Type of power analysis A priori: Compute required sample size – given α, power, and effect size			
		Determine => Powe Allocat	Tail(s) Proportion p1 Proportion p2 α err prob er (1-β err prob) tion ratio N2/N1	Two ∨ 0.05 0.30 0.05 0.8 1 1	Output Parameters Sample size group 1 Sample size group 2 Total sample size Actual power Actual α

References

- 1. Kim HY. Statistical notes for clinical researchers: sample size calculation 1. comparison of two independent sample means. *Restor Dent Endod* 2016;41:74-78.
- 2. Chow SC, Shao J, Wang H. Sample size calculations in clinical research. New York: Marcel Dekker; 2003. p81-122.

Options X-Y plot for a range of values Calculate