Chapter 379

Mixed Models Tests for Two Proportions in a 3-Level Hierarchical Design (Level-3 Randomization)

Introduction

This procedure calculates power and sample size for a three-level hierarchical mixed-effects logistic regression model which is randomized at the **third** level. The goal of the study is to compare two group proportions. The study may be cross-sectional or longitudinal.

In a *cross-sectional* version of this design, students (first level units) are nested in classrooms (second level units) which are nested in schools (third level units). Each school is randomized into one of two intervention groups, e.g., treatment and control.

In a *longitudinal* version of this design, repeated measurements (first level units) are nested in patients (second level units) which are nested in clinics (third level units). Each clinic is randomized into one of two intervention groups, e.g., treatment and control.

Note that companion procedures analyze the other cases in which the randomization occurs at the first, or second, level.

Technical Details

Our formulation comes from Ahn, Heo, and Zhang (2015), chapter 6, section 6.7.1, pages 223-225. The hierarchical mixed model used for the analysis is

$$\log\left(\frac{p_{ijk}}{1-p_{ijk}}\right) = \beta_0 + \delta X_{ijk} + u_i + u_{j(i)}$$

where

Y_{ijk}	is the binary response of the k^{th} level-1 unit of the j^{th} level-2 unit of the i^{th} level-3 unit.
p_{ijk}	is an expected value defined by $p_{ijk} = E(Y_{ijk}\|X_{ijk})$. Assume $\left[p_{ijk}\middle\|(X_{ijk}=0)\right] = p_2$ and $\left[p_{ijk}\middle\|(X_{ijk}=1)\right] = p_1$
β_0	is the fixed intercept.
δ	is the treatment effect of interest. It is the difference between the two group proportions.
X_{ijk}	is an indicator variable that is 1 if i^{th} unit is in group 1 and 0 if it is in group 2.
u_i	is the level-3 random intercept effect for the i^{th} level-3 unit. It is distributed as $N(0, \sigma_3^2)$.
$u_{j(i)}$	is the level-2 random intercept effect for the $j(i)^{th}$ level-2 unit. It is distributed as $N(0, \sigma_2^2)$.

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ρ_1 is the correlation among level-1 units which are in a particular level-2 unit. For fixed models like this, $\rho_1 = Corr(Y_{ijk}, Y_{ijk'}) = (\sigma_2^2 + \sigma_3^2)/\sigma^2$.

ρ_2 is the correlation among level-2 units which are in a particular level-3 unit. For fixed models like this, $\rho_2 = Corr(Y_{ijk}, Y_{ij'k'}) = (\sigma_3^2)/\sigma^2$.

C_1 is the number of level-3 units assigned to group 1.

C_2 is the number of level-3 units assigned to group 2.

K is the number of level-2 units per level-3 unit.

M is the number of level-1 units per level-2 unit.

The test of significance of the X_{ijk} term in the logistic model is the test statistic of interest. It tests the difference of the two group proportions.

Assume that $\delta = p_1 - p_2$ is to be tested using a z-test (large sample). The statistical hypotheses are H_0: $\delta = 0$ vs. H_a: $\delta \neq 0$. The test statistic is the regression coefficient of the X_{ijk} term in a mixed model.

The power can be calculated using

$$Power = \Phi\left\{\frac{|p_1 - p_2|\sqrt{C_2KM/f_3} - \Phi^{-1}(1-\alpha/2)\sqrt{(1+1/\lambda)\bar{p}(1-\bar{p})}}{\sqrt{p_2(1-p_2) + p_1(1-p_1)/\lambda}}\right\}$$

where $\lambda = C_1/C_2$, $\bar{p} = (C_1p_1 + C_2p_2)/(C_1 + C_2)$, and $f_3 = 1 + M(K-1)\rho_2 + (M-1)\rho_1$.

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Example 1 – Calculating Power

Suppose that a three-level hierarchical design is planned in which there will be students (level-1) which are nested in classrooms (level-2) which are nested in schools (level-3). This analysis will calculate the power for testing the significance of the difference in proportions of two interventions. There will be one measurement per student and treatments will be applied to schools (level-3 units).

The analysis will use a mixed logistic regression model. The following parameter settings are to be used for the power analysis: $P1$ = 0.6; $P2 = 0.5$; $\rho1 = 0.02$; $\rho2 = 0.01$; $K = 10$; $M = 10, 20$; $\alpha = 0.05$; and $C1 = C2$ = 6 to 12 by 2.

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	**Power**
Alpha	**0.05**
C1 (Level 3 Units Assigned to Group 1)	**6 8 10 12**
C2 (Level 3 Units Assigned to Group 2)	**C1**
K (Level 2 Units Per Level 3 Unit)	**10**
M (Level 1 Units Per Level 2 Unit)	**10 20**
P1 Input Type	**Proportions**
P1 (Group 1 Proportion|H1)	**0.6**
P2 (Group 2 Proportion)	**0.5**
ρ1 (Correlation Among Level 1 Units)	**0.02**
ρ2 (Correlation Among Level 2 Units)	**0.01**

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Output

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

Numeric Reports

Numeric Results

Solve For: Power
Groups: 1 = Treatment, 2 = Control
Hypotheses: H0: P1 = P2 vs. H1: P1 ≠ P2

	Total Sample Size	Number of Level 3 Units			Number of Level 2 Units per Level 3 Unit	Number of Level 1 Units per Level 2 Unit	Proportion			Correlation		
Power	N	Group 1 C1	Group 2 C2	Total C	K	M	Group 1 P1	Group 2 P2	Difference P1 - P2	Level 1 Units ρ1	Level 2 Units ρ2	Alpha
0.6759	1200	6	6	12	10	10	0.6	0.5	0.1	0.02	0.01	0.05
0.7896	2400	6	6	12	10	20	0.6	0.5	0.1	0.02	0.01	0.05
0.7972	1600	8	8	16	10	10	0.6	0.5	0.1	0.02	0.01	0.05
0.8915	3200	8	8	16	10	20	0.6	0.5	0.1	0.02	0.01	0.05
0.8775	2000	10	10	20	10	10	0.6	0.5	0.1	0.02	0.01	0.05
0.9466	4000	10	10	20	10	20	0.6	0.5	0.1	0.02	0.01	0.05
0.9280	2400	12	12	24	10	10	0.6	0.5	0.1	0.02	0.01	0.05
0.9747	4800	12	12	24	10	20	0.6	0.5	0.1	0.02	0.01	0.05

Power	The probability of rejecting a false null hypothesis when the alternative hypothesis is true.
N	The total number of Level-1 units.
C1, C2, and C	The number of Level-3 units assigned to groups 1, 2, and both, respectively.
K	The average number of Level-2 units per Level-3 unit.
M	The average number of Level-1 units per Level-2 unit.
P1	The proportion for group 1 (treatment group) assuming the alternative hypothesis.
P2	The proportion for group 2 (control group). This is the proportion in the standard, reference, baseline, or control group.
P1 - P2	The difference in the group proportions assumed by the alternative hypothesis.
ρ1	The correlation among Level-1 units in a particular Level-2 unit.
ρ2	The correlation among Level-2 units in a particular Level-3 unit.
Alpha	The probability of rejecting a true null hypothesis.

Summary Statements

A 2-group 3-level hierarchical design will have level-1 units (e.g., students, subjects, or patients) in level-2 units (e.g., classes, clinics, or hospitals) in level-3 units (e.g., schools, regions, or networks) with random assignment of level-3 units to each of the 2 groups (level-3 randomization). This design will be used to test the difference between two proportions, using the appropriate term of the hierarchical mixed-effects logistic regression model, with a Type I error rate (α) of 0.05. The correlation of level-1 units within a level-2 unit is assumed to be 0.02, and the correlation of level-2 units within a level-3 unit is assumed to be 0.01. To detect a proportion difference (P1 - P2) of 0.1 (with P1 = 0.6 and P2 = 0.5), with 6 level-3 units in Group 1 and 6 level-3 units in Group 2, with 10 level-2 units in each level-3 unit, and with 10 level-1 units in each level-2 unit (for a grand total of 1200 level-1 units), the power is 0.6759.

References

Ahn, C., Heo, M., and Zhang, S. 2015. Sample Size Calculations for Clustered and Longitudinal Outcomes in Clinical Research. CRC Press. New York.

This report shows the power for each of the scenarios.

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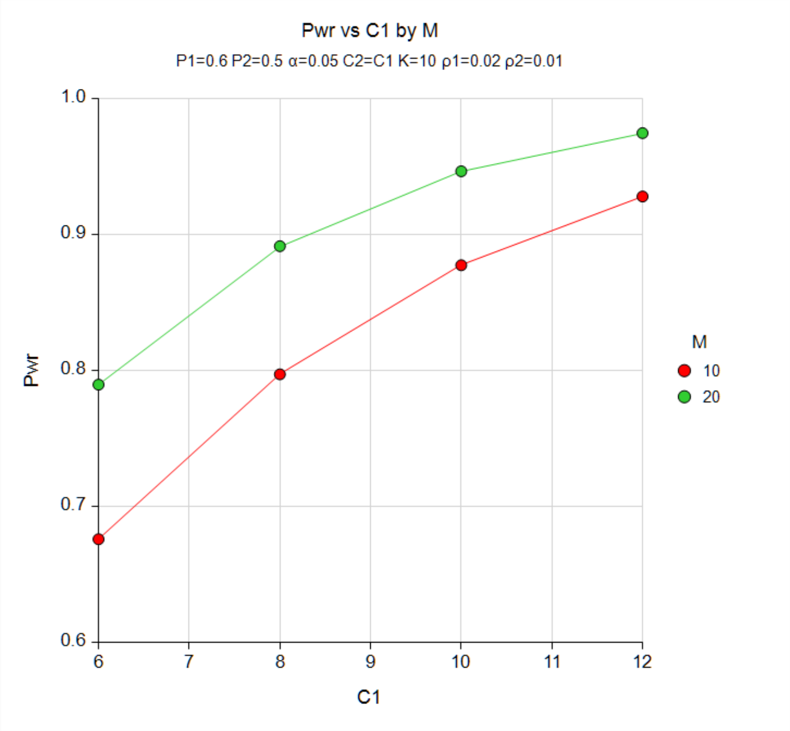
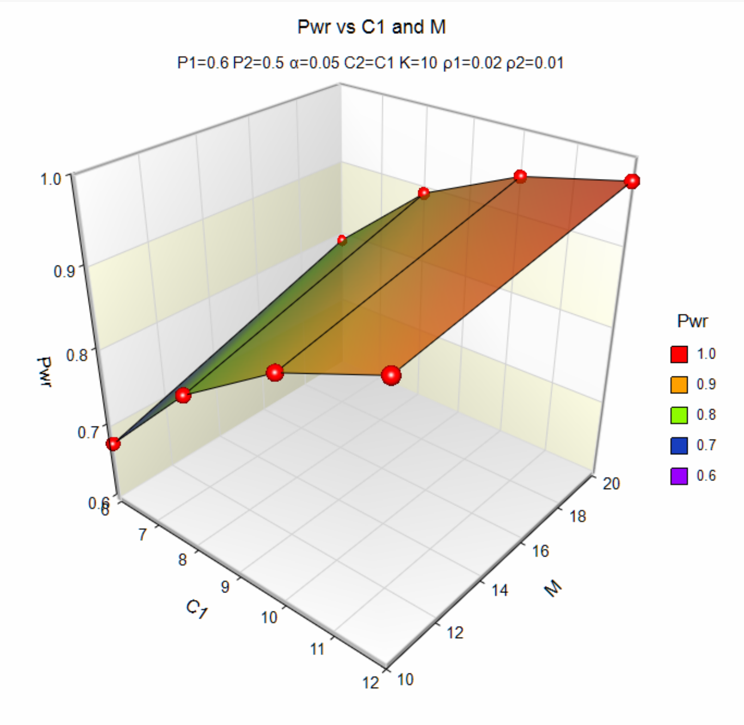
Plots Section

Plots





These plots show the power versus the level-3 count for the two values of M.

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Example 2 – Calculating Sample Size (Number of Level 3 Units)

Continuing with the last example, suppose the researchers want to determine the number of schools needed to achieve 90% power for the two values of M.

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 .... **C1 (Number Level 3 Units)**
Power... **0.90**
Alpha.. **0.05**
C2 (Level 3 Units Assigned to Group 2)......... **C1**
K (Level 2 Units Per Level 3 Unit).................. **10**
M (Level 1 Units Per Level 2 Unit) **10 20**
P1 Input Type .... **Proportions**
P1 (Group 1 Proportion|H1) **0.6**
P2 (Group 2 Proportion)................................ **0.5**
ρ1 (Correlation Among Level 1 Units)............ **0.02**
ρ2 (Correlation Among Level 2 Units)............ **0.01**

Output

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

Numeric Results

Solve For: C1 (Number Level 3 Units)
Groups: 1 = Treatment, 2 = Control
Hypotheses: H0: P1 = P2 vs. H1: P1 ≠ P2

Power	Total Sample Size N	Number of Level 3 Units Group 1 C1	Group 2 C2	Total C	Number of Level 2 Units per Level 3 Unit K	Number of Level 1 Units per Level 2 Unit M	Proportion Group 1 P1	Group 2 P2	Difference P1 - P2	Correlation Level 1 Units ρ1	Level 2 Units ρ2	Alpha
0.9058	2200	11	11	22	10	10	0.6	0.5	0.1	0.02	0.01	0.05
0.9235	3600	9	9	18	10	20	0.6	0.5	0.1	0.02	0.01	0.05

This report shows the power for each of the scenarios.

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Example 3 – Calculating Sample Size (Number of Level 2 Units per Level 3 Unit)

Continuing with the last example, suppose the researchers want to determine the number of classrooms (level-2 units) needed to achieve 90% power for *M* = 10, 20 when C1 = C2 = 10.

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 ....**K (Number Level 2 Units Per Level 3 Unit)**
Power..**0.90**
Alpha..**0.05**
C1 (Level 3 Units Assigned to Group 1).........**10**
C2 (Level 3 Units Assigned to Group 2).........**C1**
M (Level 1 Units Per Level 2 Unit) **10 20**
P1 Input Type ....**Proportions**
P1 (Group 1 Proportion|H1) **0.6**
P2 (Group 2 Proportion)................................**0.5**
ρ1 (Correlation Among Level 1 Units)...........**0.02**
ρ2 (Correlation Among Level 2 Units)...........**0.01**

Output

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

Numeric Results

Solve For: K (Number Level 2 Units Per Level 3 Unit)
Groups: 1 = Treatment, 2 = Control
Hypotheses: H0: P1 = P2 vs. H1: P1 ≠ P2

Power	Total Sample Size N	Number of Level 3 Units Group 1 C1	Group 2 C2	Total C	Number of Level 2 Units per Level 3 Unit K	Number of Level 1 Units per Level 2 Unit M	Proportion Group 1 P1	Group 2 P2	Difference P1 - P2	Correlation Level 1 Units ρ1	Level 2 Units ρ2	Alpha
0.9045	2400	10	10	20	12	10	0.6	0.5	0.1	0.02	0.01	0.05
0.9127	2800	10	10	20	7	20	0.6	0.5	0.1	0.02	0.01	0.05

This report shows the necessary value of K for each value of M.

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Example 4 – Validation using Ahn, Heo, and Zhang (2015)

Ahn, Heo, and Zhang (2015) page 226 provide a table in which several scenarios are reported. We will validate this procedure by the first row of the table. The following parameter settings were for the analysis: power = 0.80; *P1* = 0.5; *P2 = 0.4; ρ*1 *= 0.1; ρ*2 *= 0.05; K* = *4; M* = *5;* and *α = 0.05*. These settings resulted in a value of C1 and C2 (their $N_3^{(0)}$) of 42 and an attained power of 0.803.

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 .... **C1 (Number Level 3 Units)**
Power... **0.80**
Alpha.. **0.05**
C2 (Level 3 Units Assigned to Group 2).........**C1**
K (Level 2 Units Per Level 3 Unit)..................**4**
M (Level 1 Units Per Level 2 Unit) **5**
P1 Input Type ....**Proportions**
P1 (Group 1 Proportion|H1)...........................**0.5**
P2 (Group 2 Proportion)................................**0.4**
ρ1 (Correlation Among Level 1 Units)............**0.1**
ρ2 (Correlation Among Level 2 Units)............**0.05**

Output

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

Numeric Results

Solve For: C1 (Number Level 3 Units)
Groups: 1 = Treatment, 2 = Control
Hypotheses: H0: P1 = P2 vs. H1: P1 ≠ P2

		Number of Level 3 Units					Proportion			Correlation		
Power	Total Sample Size N	Group 1 C1	Group 2 C2	Total C	Number of Level 2 Units per Level 3 Unit K	Number of Level 1 Units per Level 2 Unit M	Group 1 P1	Group 2 P2	Difference P1 - P2	Level 1 Units ρ1	Level 2 Units ρ2	Alpha
0.8034	1680	42	42	84	4	5	0.5	0.4	0.1	0.1	0.05	0.05

PASS calculates the same values of C1 and power: 42 and 0.8034.

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