

Chapter 380

Mixed Models Tests for Two Means in a 3-Level Hierarchical Design (Level-1 Randomization)

Introduction

This procedure calculates power and sample size for a three-level hierarchical mixed model which is **randomized at the first level**. The goal of the study is to compare two group means. 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 student 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 repeated measurement 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 second, or third, level units.

Technical Details

Our formulation comes from Ahn, Heo, and Zhang (2015), chapter 6, section 6.3.3, pages 194-197. The hierarchical mixed model used for the analysis is

$$Y_{ijk} = \beta_0 + \delta X_{ijk} + u_i + u_{j(i)} + e_{ijk}$$

where

- Y_{ijk} is the continuous response of the k^{th} level-1 unit of the j^{th} level-2 unit of the i^{th} level-3 unit.
- β_0 is the fixed intercept.
- δ is the treatment effect of interest. It is the difference between the two group means.
- X_{ijk} is an indicator variable that is 1 if k^{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 $N(0, \sigma_u^2)$.
- $u_{j(i)}$ is the level-2 random intercept effect for the j^{th} level-2 unit. It is distributed as $N(0, \sigma_e^2)$.
- e_{ijk} is a random error term which is distributed as $N(0, \sigma_e^2)$.
- σ_u^2 is variance of the level two (cluster) random effects.
- σ_e^2 is variance of the level one (subject) random effects.

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σ^2 is the variance of Y_{ijk} , where $\sigma^2 = \sigma_e^2 + \sigma_2^2 + \sigma_3^2$.

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

C is the number of level-3 units.

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

M_1 is the number of level-1 units per level-2 unit assigned to group 1.

M_2 is the number of level-1 units per level-2 unit assigned to group 2.

The test of significance of the X_{ijk} term in the mixed model analysis is the test statistic of interest. It tests the difference of the two group means. Since these are asymptotic results, the specific type of mixed model is not stated.

Assume that $\delta = \mu_1 - \mu_2$ 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. It is given by

$$z = f((\bar{Y}_1 - \bar{Y}_2), C, K, M_1, M_2, \sigma, \rho_1)$$

where

$$\bar{Y}_g = \frac{1}{CKM} \sum_{i=1}^C \sum_{j=1}^K \sum_{k=1}^{M_g} Y_{ijk}, \quad g = 1, 2$$

The power can be calculated using

$$\text{Power} = \Phi \left\{ \left| \frac{\delta}{\sigma} \right| \sqrt{\frac{CKM_2}{f_1(1 + \frac{1}{\lambda})}} - \Phi^{-1}(1 - \alpha/2) \right\}$$

where $\lambda = M_1/M_2$ and $f_1 = 1 - \rho_1$.

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 detecting the difference between two interventions in average response for a given configuration of students, classrooms, and schools. There will be one measurement per student and the intervention will be assigned separately to each student (level-1 units).

The analysis will be a mixed model of continuous data. The following parameter settings are to be used for the power analysis: $\delta = 0.5, 0.6, 0.7$; $\sigma = 2.6$; $\rho_1 = 0.1$; $C = 5$; $K = 5$; $M1 = 5, 10, 15, 20$; $M2 = M1$, and $\alpha = 0.05$.

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
C (Level 3 Units).....	5
K (Level 2 Units Per Level 3 Unit).....	5
M1 (Level 1 Units Assigned to Group 1)	10 15 20 25
M2 (Level 1 Units Assigned to Group 2)	M1
δ (Mean Difference = $\mu_1 - \mu_2$)	0.5 0.6 0.7
σ (Standard Deviation).....	2.6
ρ_1 (Correlation Among Level 1 Units).....	0.1

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Output

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

Numeric Reports

Numeric Results for a Three-Level Hierarchical Mixed Model

Solve For: **Power**
 Groups: 1 = Treatment, 2 = Control
 Difference: $\delta = \mu_1 - \mu_2$

Power	Total Sample Size N	Number of Level 3 Units C	Number of Level 2 Units per Level 3 Unit K	Number of Level 1 Units per Level 2 Unit		Mean Difference δ	Standard Deviation σ	Correlation Among Level 1 Units ρ_1	Alpha
				Group 1 M1	Group 2 M2				
0.3604	250	5	5	5	5	0.5	2.6	0.1	0.05
0.6204	500	5	5	10	10	0.5	2.6	0.1	0.05
0.7927	750	5	5	15	15	0.5	2.6	0.1	0.05
0.8935	1000	5	5	20	20	0.5	2.6	0.1	0.05
0.4853	250	5	5	5	5	0.6	2.6	0.1	0.05
0.7763	500	5	5	10	10	0.6	2.6	0.1	0.05
0.9148	750	5	5	15	15	0.6	2.6	0.1	0.05
0.9704	1000	5	5	20	20	0.6	2.6	0.1	0.05
0.6117	250	5	5	5	5	0.7	2.6	0.1	0.05
0.8874	500	5	5	10	10	0.7	2.6	0.1	0.05
0.9730	750	5	5	15	15	0.7	2.6	0.1	0.05
0.9943	1000	5	5	20	20	0.7	2.6	0.1	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.
C	The number of Level-3 units.
K	The average number of Level-2 units per Level-3 unit.
M1 and M2	The average number of Level-1 units per Level-2 unit assigned to group 1 and 2, respectively.
δ	The mean difference in the response at which the power is calculated. $\delta = \mu_1 - \mu_2$.
σ	The standard deviation of the Level-1 responses.
ρ_1	The correlation among Level-1 units in a particular Level-2 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-1 units to each of the 2 groups (level-1 randomization). This design will be used to test the difference between two means, using the appropriate term of the hierarchical mixed-effects model, with a Type I error rate (α) of 0.05. The standard deviation of level-1 units is assumed to be 2.6. The correlation of level-1 units within a level-2 unit is assumed to be 0.1. To detect a mean difference ($\mu_1 - \mu_2$) of 0.5, with 5 level-3 units, with 5 level-2 units in each level-3 unit, and within each level-2 unit, 5 level-1 units in Group 1 and 5 level-1 units in Group 2 (for a grand total of 250 level-1 units), the power is 0.3604.

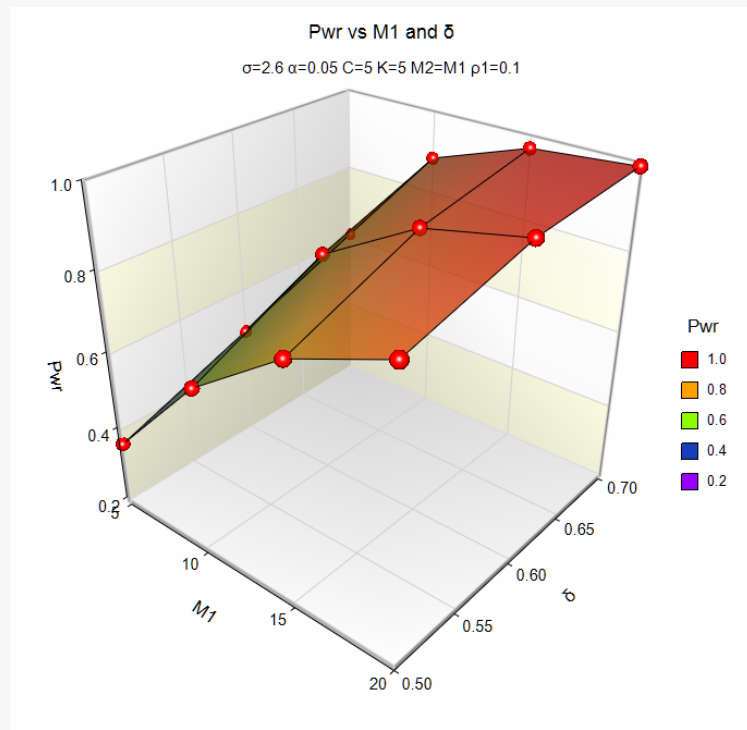
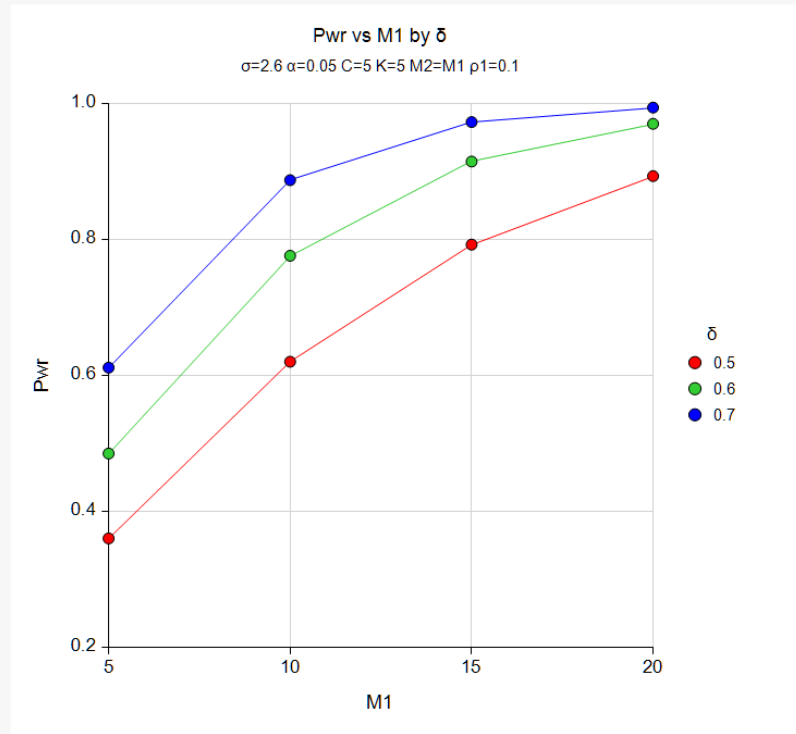
References

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.

Plots Section

Plots



These plots show the power for various other parameter settings.

Example 2 – 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 clusters needed to achieve 90% power for the 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 **K (Number Level 2 Units Per Level 3 Unit)**
 Power..... **0.90**
 Alpha..... **0.05**
 C (Level 3 Units)..... **5**
 M1 (Level 1 Units Assigned to Group 1) **10 15 20 25**
 M2 (Level 1 Units Assigned to Group 2) **M1**
 δ (Mean Difference = $\mu_1 - \mu_2$) **0.5 0.6 0.7**
 σ (Standard Deviation)..... **2.6**
 ρ_1 (Correlation Among Level 1 Units)..... **0.1**

Output

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

Numeric Results for a Three-Level Hierarchical Mixed Model

Solve For: **K (Number Level 2 Units Per Level 3 Unit)**
 Groups: 1 = Treatment, 2 = Control
 Difference: $\delta = \mu_1 - \mu_2$

Power	Total Sample Size N	Number of Level 3 Units C	Number of Level 2 Units per Level 3 Unit K	Number of Level 1 Units per Level 2 Unit		Mean Difference δ	Standard Deviation σ	Correlation Among Level 1 Units ρ_1	Alpha
				Group 1 M1	Group 2 M2				
0.9073	1050	5	21	5	5	0.5	2.6	0.1	0.05
0.9195	1100	5	11	10	10	0.5	2.6	0.1	0.05
0.9073	1050	5	7	15	15	0.5	2.6	0.1	0.05
0.9396	1200	5	6	20	20	0.5	2.6	0.1	0.05
0.9148	750	5	15	5	5	0.6	2.6	0.1	0.05
0.9306	800	5	8	10	10	0.6	2.6	0.1	0.05
0.9148	750	5	5	15	15	0.6	2.6	0.1	0.05
0.9306	800	5	4	20	20	0.6	2.6	0.1	0.05
0.9143	550	5	11	5	5	0.7	2.6	0.1	0.05
0.9352	600	5	6	10	10	0.7	2.6	0.1	0.05
0.9352	600	5	4	15	15	0.7	2.6	0.1	0.05
0.9352	600	5	3	20	20	0.7	2.6	0.1	0.05

This report shows the required value of K for each of the scenarios.

Example 3 – Validation using Ahn, Heo, and Zhang (2015)

Ahn, Heo, and Zhang (2015) page 198 provide a table in which several scenarios are reported. We will validate this procedure by reproducing the first row of the table. The following parameter settings were used for the first row of the table: power = 0.80; $\delta = 0.3$; $\sigma = 1$; $\rho_1 = 0.1$; $C = 8$; $K = 4$; and $\alpha = 0.05$. These settings resulted in a value of M1 and M2 (their $N_1^{(0)}$) of 5 and an attained power of 0.807.

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	M1 (Number Level 1 Units Per Level 2 Unit)
Power.....	0.80
Alpha.....	0.05
C (Level 3 Units).....	C1
K (Level 2 Units Per Level 3 Unit).....	4
M2 (Level 1 Units Assigned to Group 2)	M1
δ (Mean Difference = $\mu_1 - \mu_2$)	0.3
σ (Standard Deviation).....	1
ρ_1 (Correlation Among Level 1 Units).....	0.1
ρ_2 (Correlation Among Level 2 Units).....	0.05

Output

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

Numeric Results for a Three-Level Hierarchical Mixed Model										
Solve For: M1 (Number Level 1 Units Per Level 2 Unit)										
Groups: 1 = Treatment, 2 = Control										
Difference: $\delta = \mu_1 - \mu_2$										
Power	Total Sample Size N	Number of Level 3 Units C	Number of Level 2 Units per Level 3 Unit K	Number of Level 1 Units per Level 2 Unit		Mean Difference δ	Standard Deviation σ	Correlation Among Level 1 Units ρ_1	Alpha	
				Group 1 M1	Group 2 M2					
0.8074	320	8	4	5	5	0.3	1	0.1	0.05	

PASS calculates the same values of M1 and power: 5 and 0.8074.