Chapter 382

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

Introduction

This procedure calculates power and sample size for a three-level hierarchical mixed model which is **randomized at the third 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 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 units.

Technical Details

Our formulation comes from Ahn, Heo, and Zhang (2015), chapter 6, section 6.3.1, pages 189-191. 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 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^{th} level-2 unit. It is distributed as $N(0, \sigma_2^2)$.
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.

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, $\rho_1 = Corr(Y_{ijk}, Y_{ijk'}) = (\sigma_2^2 + \sigma_3^2)/\sigma^2$.

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 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 $H_0\colon \delta = 0$ vs. $H_a\colon \delta \neq 0$. The test statistic is the regression coefficient of the X_{ijk} term in a mixed model. It is given by

$$z = f\left((\bar{Y}_1 - \bar{Y}_2), C_1, C_2, K, M, \sigma, \rho_1, \rho_2\right)$$

where

$$\bar{Y}_g = \frac{1}{C_g KM} \sum_{i=1}^{C_g} \sum_{j=1}^{K} \sum_{k=1}^{M} Y_{ijk}, \qquad g = 1,2$$

The power can be calculated using

$$Power = \Phi\left\{\left|\frac{\delta}{\sigma}\right| \sqrt{\frac{C_2 KM}{\left[f_3(1 + \frac{1}{\lambda})\right]}} - \Phi^{-1}(1 - \alpha/2)\right\}$$

where $\lambda = C_1/C_2$ and $f_3 = 1 + M(K-1)\rho_2 + (M-1)\rho_1$.

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 treatments will be applied to schools (level-3 units).

The analysis will be a mixed model of continuous data. The following parameter settings are to be used for the power analysis: $\delta = 0.6$; $\sigma = 2.6$; $\rho 1 = 0.1$; $\rho 2 = 0.05$; $K = 10$; $M = 10, 20,$ or 30; $\alpha = 0.05$; and $C1 = C2 = 10$ to 25 by 5.

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)......... **10 15 20 25**
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 30**
δ (Mean Difference = μ1 – μ2)....................... **0.6**
σ (Standard Deviation).................................. **2.6**
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 Reports

Numeric Results for a Three-Level Hierarchical Mixed Model

Solve For: Power
Groups: 1 = Treatment, 2 = Control
Difference: δ = μ1 - μ2

Power	Total Sample Size N	Number of Level 3 Units Group 1 C1	Number of Level 3 Units Group 2 C2	Number of Level 2 Units per Level 3 Unit K	Number of Level 1 Units per Level 2 Unit M	Mean Difference δ	Standard Deviation σ	Correlation Level 1 Units ρ1	Correlation Level 2 Units ρ2	Alpha
0.5318	2000	10	10	10	10	0.6	2.6	0.1	0.05	0.05
0.5618	4000	10	10	10	20	0.6	2.6	0.1	0.05	0.05
0.5725	6000	10	10	10	30	0.6	2.6	0.1	0.05	0.05
0.7048	3000	15	15	10	10	0.6	2.6	0.1	0.05	0.05
0.7360	6000	15	15	10	20	0.6	2.6	0.1	0.05	0.05
0.7467	9000	15	15	10	30	0.6	2.6	0.1	0.05	0.05
0.8224	4000	20	20	10	10	0.6	2.6	0.1	0.05	0.05
0.8489	8000	20	20	10	20	0.6	2.6	0.1	0.05	0.05
0.8577	12000	20	20	10	30	0.6	2.6	0.1	0.05	0.05
0.8971	5000	25	25	10	10	0.6	2.6	0.1	0.05	0.05
0.9170	10000	25	25	10	20	0.6	2.6	0.1	0.05	0.05
0.9233	15000	25	25	10	30	0.6	2.6	0.1	0.05	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 and C2	The number of Level-3 units assigned to groups 1 and 2, 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.
δ	The mean difference in the response at which the power is calculated. δ = μ1 - μ2.
σ	The standard deviation of the Level-1 responses.
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 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, and the correlation of level-2 units within a level-3 unit is assumed to be 0.05. To detect a mean difference (μ1 - μ2) of 0.6, with 10 level-3 units in Group 1 and 10 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 2000 level-1 units), the power is 0.5318.

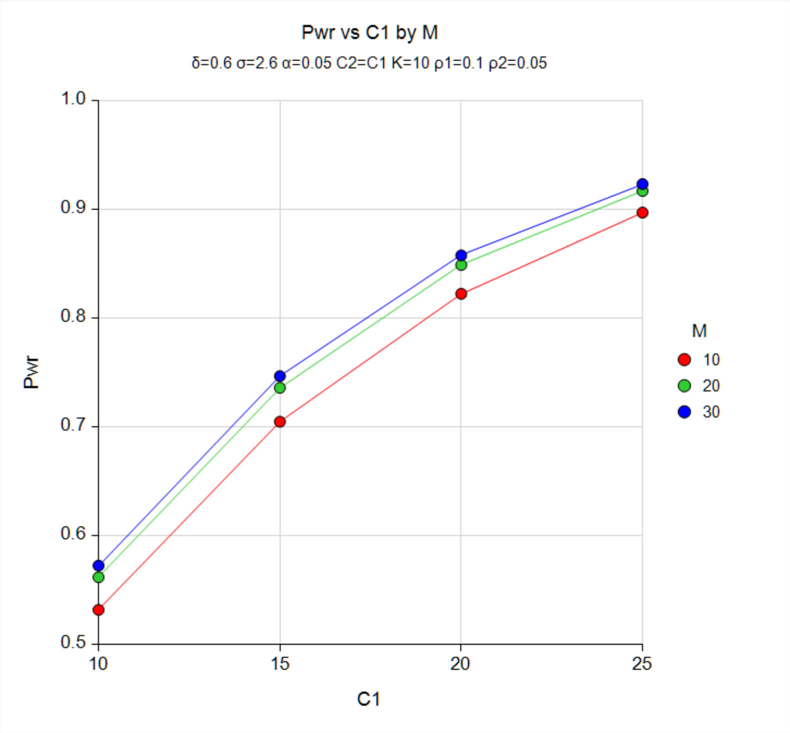
References

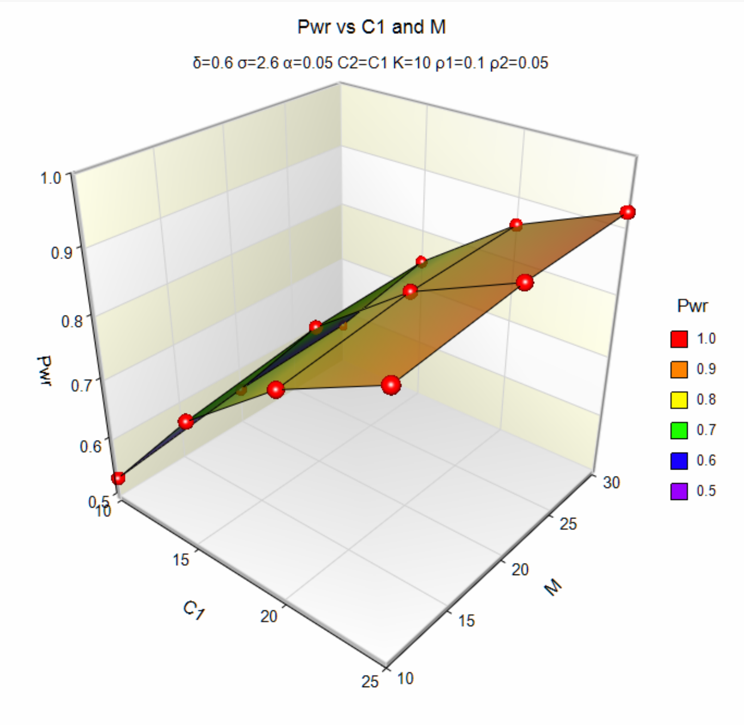
Ahn, C., Heo, M., and Zhang, S. 2015. Sample Size Calculations for Clustered and Longitudinal Outcomes in Clinical Research. CRC Press. New York.

This report shows the power for each of the scenarios.

Plots Section

Plots





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

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

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 ....**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 30**
δ (Mean Difference = μ1 – μ2)......................**0.6**
σ (Standard Deviation)..................................**2.6**
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 for a Three-Level Hierarchical Mixed Model

Solve For: C1 (Number Level 3 Units)
Groups: 1 = Treatment, 2 = Control
Difference: δ = μ1 - μ2

		Number of Level 3 Units						Correlation		
Power	Total Sample Size N	Group 1 C1	Group 2 C2	Number of Level 2 Units per Level 3 Unit K	Number of Level 1 Units per Level 2 Unit M	Mean Difference δ	Standard Deviation σ	Level 1 Units ρ1	Level 2 Units ρ2	Alpha
0.9081	5200	26	26	10	10	0.6	2.6	0.1	0.05	0.05
0.9061	9600	24	24	10	20	0.6	2.6	0.1	0.05	0.05
0.9014	13800	23	23	10	30	0.6	2.6	0.1	0.05	0.05

This report shows the power for each of the scenarios.

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, 30 when C1 = C2 = 30.

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)......... **30**
C2 (Level 3 Units Assigned to Group 2)......... **C1**
M (Level 1 Units Per Level 2 Unit) **10 20 30**
δ (Mean Difference = μ1 – μ2)....................... **0.6**
σ (Standard Deviation).................................. **2.6**
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 for a Three-Level Hierarchical Mixed Model

Solve For: K (Number Level 2 Units Per Level 3 Unit)
Groups: 1 = Treatment, 2 = Control
Difference: δ = μ1 - μ2

		Number of Level 3 Units						Correlation		
Power	Total Sample Size N	Group 1 C1	Group 2 C2	Number of Level 2 Units per Level 3 Unit K	Number of Level 1 Units per Level 2 Unit M	Mean Difference δ	Standard Deviation σ	Level 1 Units ρ1	Level 2 Units ρ2	Alpha
0.9100	3600	30	30	6	10	0.6	2.6	0.1	0.05	0.05
0.9084	4800	30	30	4	20	0.6	2.6	0.1	0.05	0.05
0.9219	7200	30	30	4	30	0.6	2.6	0.1	0.05	0.05

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

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

Ahn, Heo, and Zhang (2015) page 192 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; δ = 0.3; $\sigma = 1$; $\rho 1 = 0.1$; $\rho 2 = 0.05$; $K = 4$; $M = 5$; and $\alpha = 0.05$. These settings resulted in a value of C1 and C2 (their $N_3^{(0)}$) of 19 and an attained power of 0.805.

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**
δ (Mean Difference = μ1 – μ2)...................... **0.3**
σ (Standard Deviation).................................. **1**
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 for a Three-Level Hierarchical Mixed Model

Solve For: C1 (Number Level 3 Units)
Groups: 1 = Treatment, 2 = Control
Difference: δ = μ1 - μ2

		Number of Level 3 Units						Correlation		
Power	Total Sample Size N	Group 1 C1	Group 2 C2	Number of Level 2 Units per Level 3 Unit K	Number of Level 1 Units per Level 2 Unit M	Mean Difference δ	Standard Deviation σ	Level 1 Units ρ1	Level 2 Units ρ2	Alpha
0.8052	760	19	19	4	5	0.3	1	0.1	0.05	0.05

PASS calculates the same values of C1 and power: 19 and 0.8052.