

Bases Éticas Metodológicas e Gerenciais em Pesquisa MPT5795

Cálculo do Tamanho da Amostra



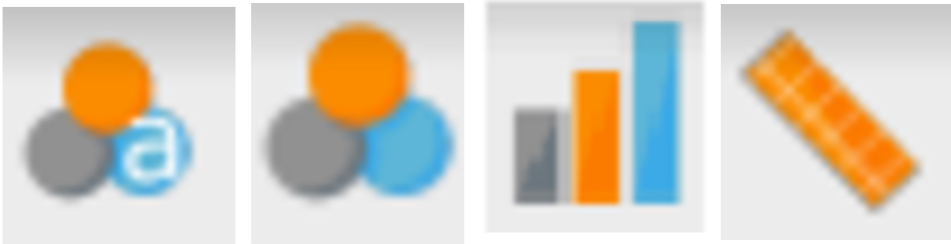


Amostragem

População

Grupo I

Grupo C



Início

Fim

Etapa 1

P

Critérios de Inclusão & Critérios de Exclusão que definem a população

I

Novo tratamento/intervenção a ser comparado com outra terapêutica ou prática de interesse

C

O

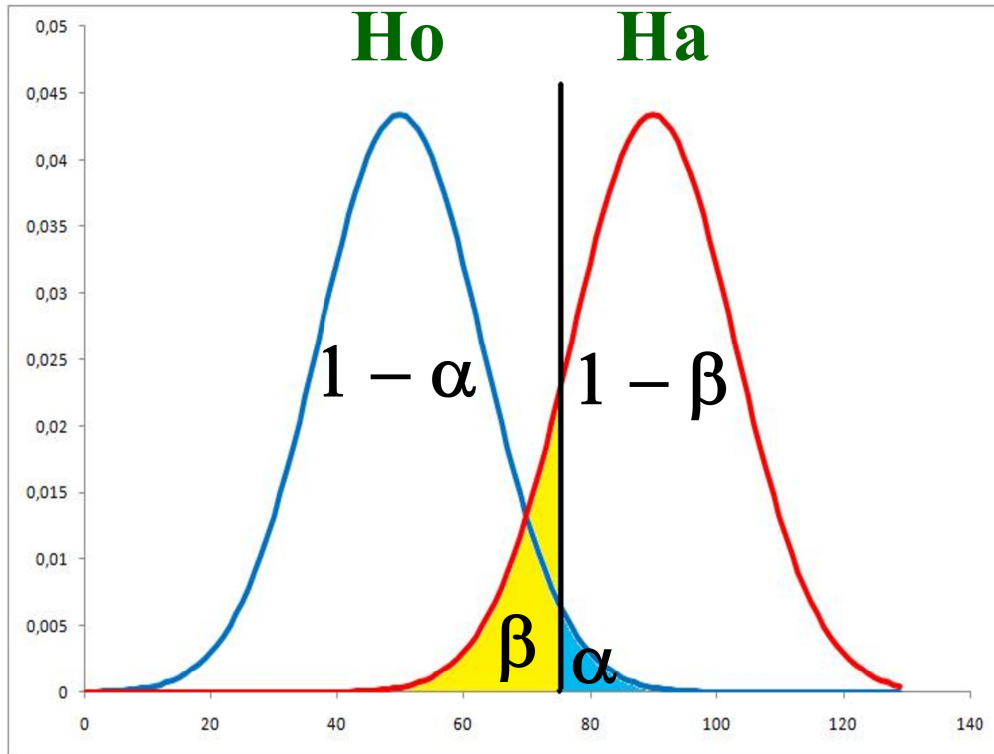
Desfechos mensuráveis (“outcomes”) que permitam verificar o efeito

T

Tempos de coleta das variáveis e de observação dos efeitos

“A Realidade”

“o estudo”	H_0 é Verdadeira	H_0 é Falsa
Aceitar H_0	Decisão Correta	Erro Tipo II (β)
Rejeitar H_0	Erro tipo I (α)	Decisão Correta



Etapa 2

Planejamento Estatístico relativo às variáveis

Análise Univariada

- Teste t
- Anova
- Teste de Wilcoxon
- Teste de Mann-Whitney

Análise Bivariada

- Teste χ^2
- Teste Exato de Fisher
- Correlação de Pearson
- Correlação de Spearman

Análise Multivariada

- Regressão Múltipla
- Análise Fatorial
- Regressão Logística

Desfecho Primário ou Desfecho Principal

Quantitativa
Contínua

$$H_0 : \bar{X}_S \leq \bar{X}_E$$

$$H_A : \bar{X}_S > \bar{X}_E$$

Qualitativa
Ordinal

$$H_0 : R_S \leq R_E$$

$$H_A : R_S > R_E$$

Qualitativa
Nominal

$$H_0 : P_S \leq P_E$$

$$H_A : P_S > P_E$$

Etapa 3 – Cálculo do Tamanho da Amostra

Regra Geral

- Partir da fórmula de estimativa do erro e isolar n
- Abordagem pelo Erro Padrão da Média foi uma das primeiras formas de cálculo do tamanho da amostra

$$EPM = \frac{S}{\sqrt{n}}$$

isolar n

$$n = \frac{S^2}{EPM^2}$$

Incluir o nível de significância e o poder estatístico

$$n = (z_{\alpha} + z_{\beta})^2 \frac{S^2}{EPM^2}$$

- Teste t para duas amostras independentes

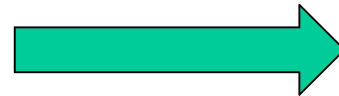
$$t = \frac{\overline{X}_A - \overline{X}_B}{EPM_D}$$



$$t = \frac{\overline{X}_A - \overline{X}_B}{\sqrt{\frac{S_A^2}{n_A} + \frac{S_B^2}{n_B}}}$$

- t pode ser traduzido em termos de α e β
- As variâncias (S^2) e o tamanho de cada amostra (n) podem ser iguais

$$(t_\alpha + t_\beta) = \frac{d}{\sqrt{2 \frac{S^2}{n}}}$$



$$n = \frac{2(t_\alpha + t_\beta)^2 S^2}{d^2}$$

Tamanho da Amostra

Cálculo por Software

Test family

- t tests
- Exact
- F tests
- t tests
- χ^2 tests
- z tests

G*Power 3.1.9.4

File Edit View Tests Calculator Help

Central and noncentral distributions Protocol of power analyses

Test family: t tests

Statistical test: Means: Difference between two independent means (two groups)

Type of power analysis: A priori: Compute required sample size - given α , power, and effect size

Input Parameters

Tail(s)	One
Effect size d	0.5
α err prob	0.05
Power (1- β err prob)	0.95
Allocation ratio N2/N1	1

X-Y plot for a range of values

Calculate

Statistical test

- Means: Difference between two independent means (two groups)
- Correlation: Point biserial model
- Linear bivariate regression: One group, size of slope
- Linear bivariate regression: Two groups, difference between intercepts
- Linear bivariate regression: Two groups, difference between slopes
- Linear multiple regression: Fixed model, single regression coefficient
- Means: Difference between two dependent means (matched pairs)
- Means: Difference between two independent means (two groups)
- Means: Difference from constant (one sample case)
- Means: Wilcoxon signed-rank test (matched pairs)
- Means: Wilcoxon signed-rank test (one sample case)
- Means: Wilcoxon-Mann-Whitney test (two groups)
- Generic t test

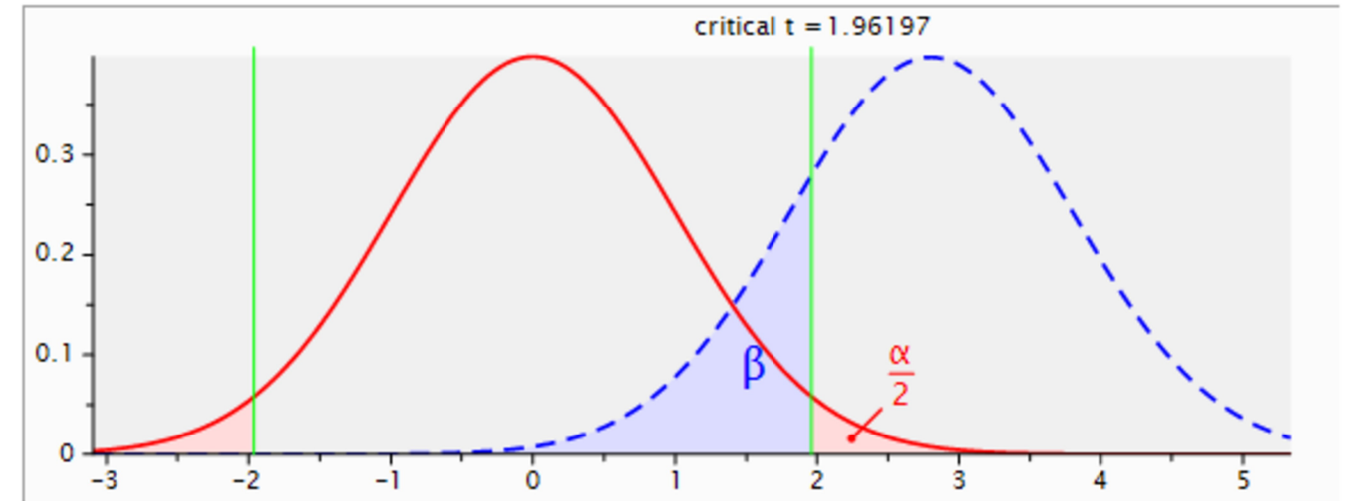
Type of power analysis

- A priori: Compute required sample size - given α , power, and effect size
- A priori: Compute required sample size - given α , power, and effect size
- Compromise: Compute implied α & power - given β/α ratio, sample size, and effect size
- Criterion: Compute required α - given power, effect size, and sample size
- Post hoc: Compute achieved power - given α , sample size, and effect size
- Sensitivity: Compute required effect size - given α , power, and sample size

Exemplo – teste t para 2 grupos independentes

Estudo Piloto – Pacientes Transplante Hepático

Encefalopatia Hepática	Creatinina	
	Nao	Sim
Valid	83	46
Mean	0.908	0.967
Std. Deviation	0.381	0.328
Minimum	0.430	0.510
Maximum	3.130	1.800



Test family: t tests

Statistical test: Means: Difference between two independent means (two groups)

Type of power analysis: A priori: Compute required sample size - given α , power, and effect size

Input Parameters:

- Tail(s): Two
- Effect size d: 0.163
- α err prob: 0.05
- Power ($1 - \beta$ err prob): 0.80
- Allocation ratio N2/N1: 1

Output Parameters:

- Noncentrality parameter δ : 2.8043580
- Critical t: 1.9619730
- Df: 1182
- Sample size group 1: 592
- Sample size group 2: 592
- Total sample size: 1184
- Actual power: 0.8001391

Independent Samples T-Test

	t	df	p	Cohen's d
Creatinina	-0.886	127	0.377	-0.163

Note. Student's t-test.

Poder ($1 - \beta$) = 0.5392447

Exemplo – teste de Mann-Whitney (2 grupos independentes)

Estudo Piloto - Pacientes Transplante Hepático

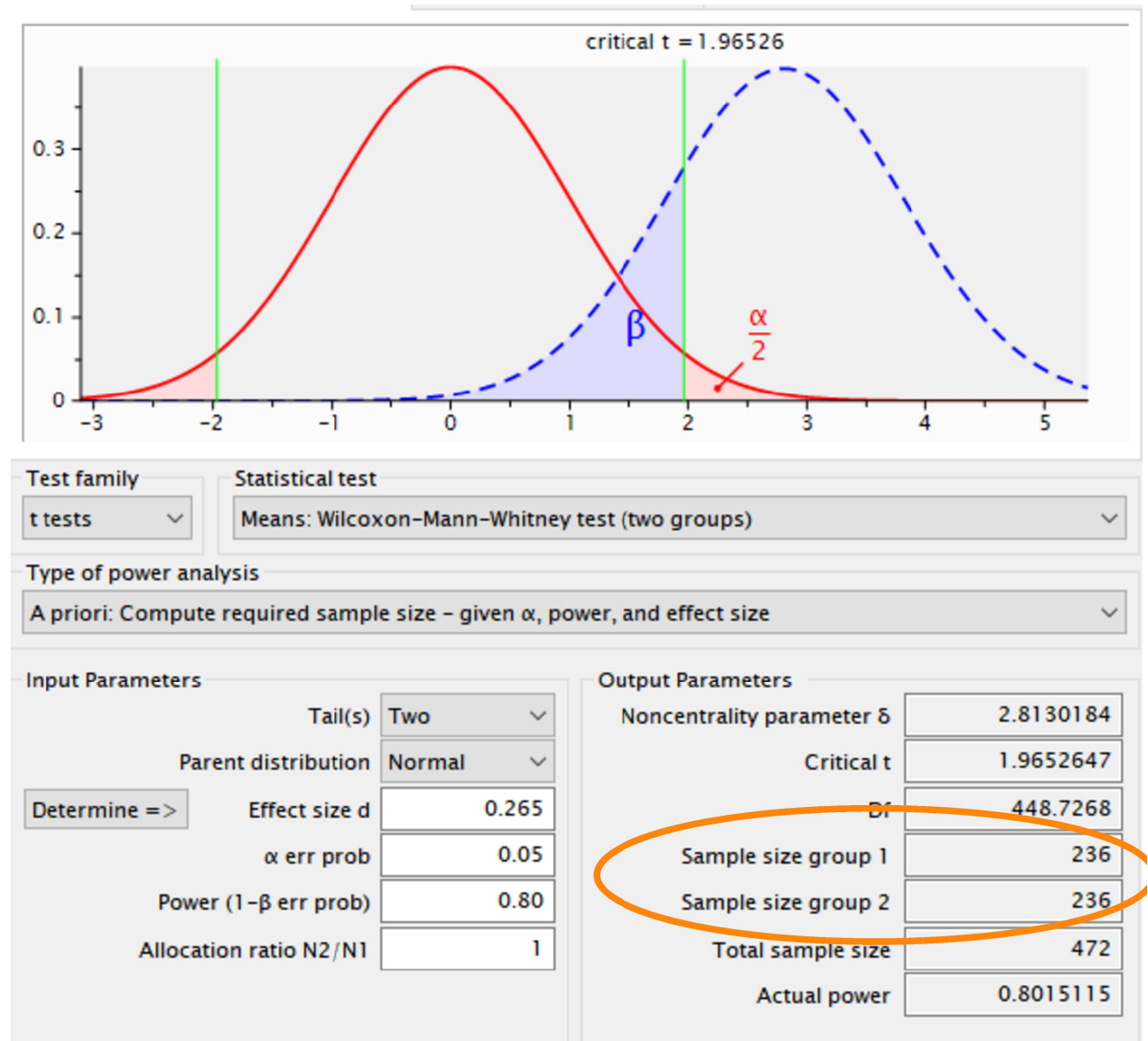
	CHILD_Score	
	Nao	Sim
Carcinoma Hepatocelular		
Valid	113	16
Median	8.000	6.500
Minimum	5.000	5.000
Maximum	11.000	10.000

Mann-Whitney U test

	W	p	Rank-Biserial Correlation
CHILD_Score	1144	0.082	0.265

Note. Effect size is given by the rank biserial correlation.

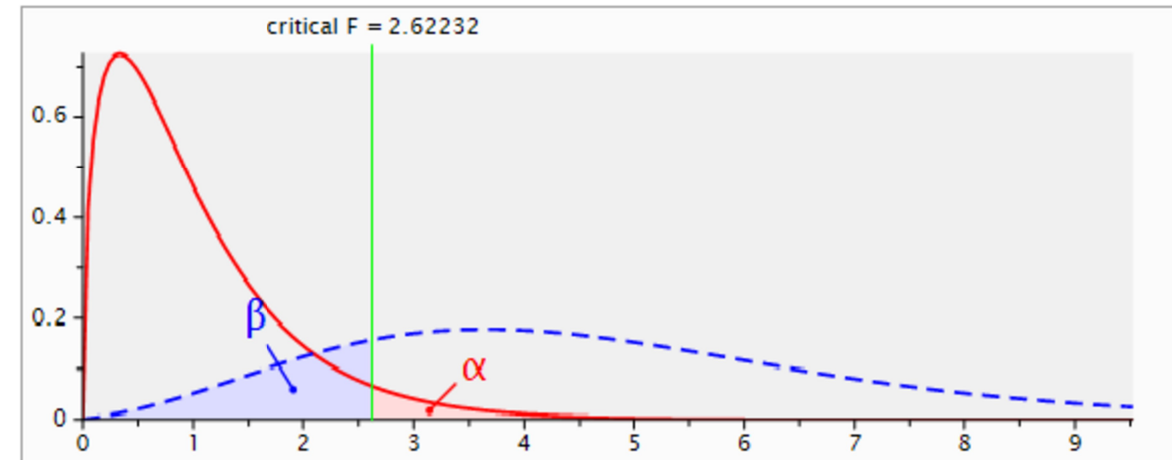
$$\text{Poder } (1 - \beta) = 0.1608414$$



Estudo Piloto - MELD pacientes transplante hepático

TipagemABO	Mean	SD	N
A	12.745	4.106	55
AB	14.000	3.464	3
B	14.235	4.590	17
O	13.796	4.035	54

Exemplo – ANOVA (um fator)



Test family: F tests

Statistical test: ANOVA: Fixed effects, omnibus, one-way

Type of power analysis: A priori: Compute required sample size – given α, power, and effect size

Input Parameters:

- Determine =>
- Effect size f: 0.146
- α err prob: 0.05
- Power (1-β err prob): 0.8
- Number of groups: 4

Output Parameters:

- Noncentrality parameter λ: 10.9990560
- Critical F: 2.6223153
- Numerator df: 3
- Denominator df: 512
- Total sample size: 516
- Actual power: 0.8005148

$$f = \sqrt{\frac{\eta^2}{(1-\eta^2)}}$$

ANOVA - MELD

Cases	Sum of Squares	df	Mean Square	F	p	η^2_p
TipagemABO	44.97	3	14.99	0.878	0.455	0.021
Residuals	2134	125	17.07			f 0.146

Note. Type III Sum of Squares

$$\text{Power } (1-\beta) = 0.2467165$$

Tamanho do efeito
f de Cohen

Estudo Piloto – pacientes transplante hepático

HCV		encefalopatia		Total
		Sim	Nao	
Positivo	Count	11	33	44
	% row	25%	75 %	100 %
Negativo	Count	35	50	85
	% row	41.18 %	58.82 %	100 %
Total	Count	46	83.000	129
	% row	35.66%	64.34%	100%

Chi-Squared Tests

	Value	df	p
χ^2			
continuity correction	2.639	1	0.104
N	129		
Poder $(1-\beta) = 0.3890296$			

$$w = \phi$$

$$w = \sqrt{\frac{\chi^2}{N}}$$

Exemplo – Tabela de Contingência

Tabelas 2 x 2

Test family: Exact
 Statistical test: Proportions: Inequality, two independent groups (Fisher's exact test)
 Type of power analysis: A priori: Compute required sample size – given α , power, and effect size
 Input Parameters:
 Tail(s): Two
 Proportion p1: 0.25
 Proportion p2: 0.41
 α err prob: 0.05
 Power (1- β err prob): 0.80
 Allocation ratio N2/N1: 1
 Output Parameters:
 Sample size group 1: 146
 Sample size group 2: 146
 Total sample size: 292
 Actual power: 0.8030133
 Actual α : 0.0374707

Qualquer Tabela de Contingência (DF e w)

Test family: χ^2 tests
 Statistical test: Goodness-of-fit tests: Contingency tables
 Type of power analysis: A priori: Compute required sample size – given α , power, and effect size
 Input Parameters:
 Effect size w: 0.143
 α err prob: 0.05
 Power (1- β err prob): 0.80
 Df: 1
 Output Parameters:
 Noncentrality parameter λ : 7.8524160
 Critical χ^2 : 3.8414588
 Total sample size: 384
 Actual power: 0.8661776

Tamanho da Amostra

Estudo Piloto – Pacientes Transplante Hepático

	N	Mean	SD	SE
Albumina	129	3.463	0.581	0.051
IMC	129	27.671	5.184	0.456

IMC x Albumina

Model	R	R ²	Adjusted R ²	RMSE
H ₀	0.000	0.000	0.000	0.581
H ₁	0.113	0.013	0.005	0.580

$$f^2 = \frac{R^2}{(1-R^2)}$$

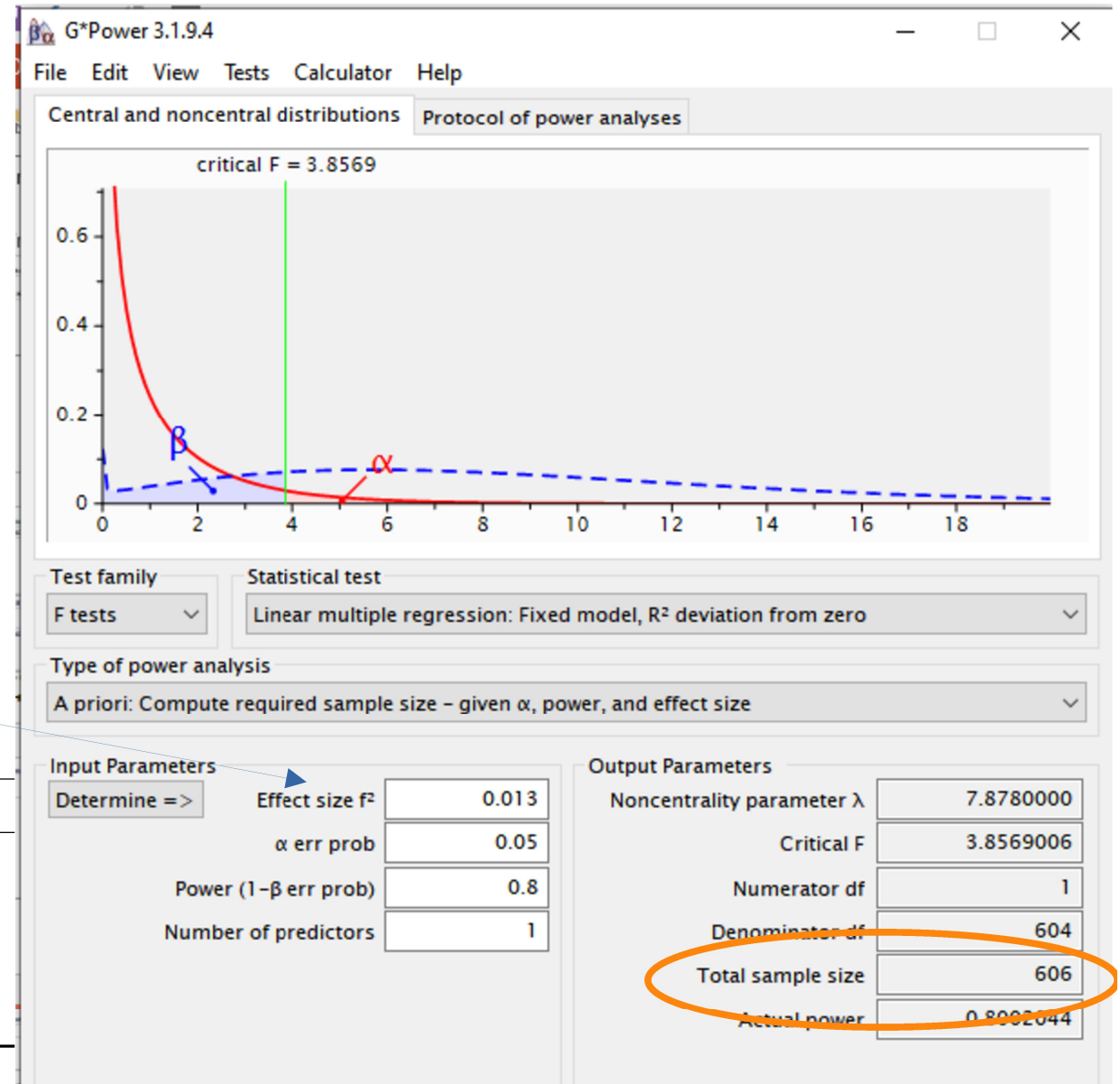
Tamanho do Efeito f² de Cohen

ANOVA

Model		Sum of Squares	df	Mean Square	F	p
H ₁	Regression	0.551	1	0.551	1.637	0.203
	Residual	42.731	127	0.336		
	Total	43.281	128			

Note. The intercept model is omitted, as no meaningful information can be shown.

Exemplo – Correlação



Estudo Piloto – Pacientes Transplante Hepático

	N	Mean	SD	SE
Albumina	129	3.463	0.581	0.051
IMC	129	27.671	5.184	0.456

Coefficients

Model		Unstandardized	Standard Error	Standardized	t	p
H ₀	(Intercept)	3.463	0.051		67.636	4.845e -102
H ₁	(Intercept)	3.813	0.278		13.697	8.757e -27
	IMC	-0.013	0.010	-0.113	-1.280	0.203

Exemplo – Correlação 2

