

Statistical analysis plan and sample size calculation

Official Title:

The Effect of Chronic Nitrate Supplementation on Acute Mountain Sickness and Exercise Performance in Hypoxia

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High-altitude headache

RM ANOVA

2x4 RM ANOVA = Total of 8 repeated measures

	Av correlation		Meaningful difference	Effect size		Sample size
	Calculated	Table		Calculated	Table	
Hypoxia	0.6	Strong = 0.5	14	0.7	Large = 0.57	14
			10	0.5	Medium = 0.35	23
All data	0.2	Weak = 0.3	14	0.7	Large = 0.49	16
			10	0.5	Large = 0.49	16
4 measures	0.4	Weak = 0.3	10	0.7	Large = 0.49	16

Calculations (4 measures)

Average correlation

		Hypoxic			Normoxic
		4 h	6 h	8 h	8 h
Hypoxic	4 h	1	0.4	0.4	
	6 h		1	0.9	
	8 h			1	-0.3
Normoxic	8 h				1

Average correlation = 0.4

Effect size

Meaningful difference = 10

SD of difference (4-6 h in hypoxia) = 18

Cohen's D = 0.55

Conversion to RM ANOVA effect size = $0.55 / (\text{SQRT}(1-0.4)) = 0.7$

(Stevens, 2002)

A sample size estimation for this analysis indicated that 16 participants were needed to produce an 80% chance of obtaining statistical significance at the 0.05 level (5), based on a minimum important difference of 10 mm (2), a standard deviation of the difference of 18 mm, and an estimated average correlation of 0.4 (data from (3)).

Time to exhaustion

t tests – Means: Difference between two dependent means (matched pairs)

Analysis: A priori: Compute required sample size

Input:	Tail(s)	=	Two
	Effect size dz	=	0.9090909
	α err prob	=	0.05
	Power (1- β err prob)	=	0.8
Output:	Noncentrality parameter δ	=	3.1491833
	Critical t	=	2.2009852
	Df	=	11
	Total sample size	=	12
	Actual power	=	0.8174086

The effect of nitrate supplementation on maximal exercise performance (TTE) was determined by paired samples t-test. A sample size estimation for this analysis indicated that 12 participants were needed to produce an 80% chance of obtaining statistical significance at the 0.05 level for a two-tailed design (1), based on a minimum important difference of 30 seconds and a standard deviation of the difference of 33 seconds (data from (4)). Given the smaller required sample size for this analysis, only 15 participants completed the TTE component of the study.

References

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