

Exam SPO-3055, December 2011

Task I

Define internal and external validity and come up with threats to both when you have a study where you measure maximal oxygen uptake before and after a training program over 3 years in a group of obese, untrained subjects 13 years of age.

Task II

You are about to design a study where you would like to determine whether a high fat/low carbohydrate diet influence exercise capacity and vascular function.

Design the study and write a:

1. Research protocol (maximum 3 pages including references)
2. Informed consent (maximum 3 pages)
3. And discuss the following ethical concerns from the ethical committee application
 - a. Research ethical challenges with the project
 - i. Advantages in participation for:
 1. Subjects
 2. Group of persons
 3. Society
 4. Science
 - ii. Disadvantages for:
 1. Subjects
 2. Group of persons
 - b. Discuss actions you will take to secure and protect your subjects
 - c. Discuss how to secure and store data and maintain subject confidentiality
4. You have performed the study and you are about to write the paper to get it published into an international journal. What is required to become a co-author on your paper?

Task III

You are about to design a study where you compare the effect of two programs of endurance training upon maximal oxygen uptake; interval training (10x1 minutes) or a isocaloric program of moderate continuous exercise.

You are given the following information: A clinical relevant difference in maximal oxygen uptake between two groups is 3 ml/kg/min and standard deviation for measuring maximal oxygen uptake in your laboratory is 5 ml/kg/min. Use power of 0.90 and (a two-tailed) p-value less than 0.1

How many subjects do you need in each group to detect a real difference in training response between the two programs?

Task IV

We have got a new system (OxyNew) for measuring maximal oxygen uptake in the laboratory that is much easier to use than the old apparatus (Gold Standard). The following data for maximal oxygen uptake were collected (data are in mL/kg/min):

Gold Standard	OxyNew
55	50
60	66
25	32
36	33
87	89
85	86
33	42
24	24
11	16
55	55
56	66
58	53
59	56
70	90
82	86
78	94
67	78
68	66
67	72
72	66
54	48
37	37
44	46
42	52
39	38
33	30
33	39
32	26
28	35
24	30
41	48
42	34
53	56
57	52

How would you evaluate the strength of relation and agreement between the results for the two systems? Plot this in figures and gives numbers and explain why one expression form may be better than the other.