

Sample Size and Randomization Assignment

Due: **Fri Feb 5 by 5pm**, uploaded to Moodle as PDF and Excel documents

The answers to all questions should go in the PDF document; the pilot data and randomization should go in the Excel file.

Part One: Sample Size

Your client would like to see how Pressure Pain Threshold Biceps changes between two readings, one taken immediately after the other. They would like to be able to detect a difference of 5 kPa, and are hopeful that 30 individuals are enough.

1. What additional information do you need from your client? Assume the usual answers.
2. What additional information do you need from a pilot study? Perform a pilot study on some Islanders to obtain this additional information. Put the data in the first tab of your Excel file.
3. Calculate the minimal detectable difference with 30 in each group. Compute this by hand (except for numerical calculations), showing your work, and check with a software program of your choice. Is a sample size of 30 too many, or not enough? What are the disadvantages of having too many? What are the disadvantages of having too few?
4. Calculate the sample size they need to detect their desired difference, using a software program of your choice. Write a few sentences describing what software you used and exactly how you used it.
5. Now suppose they want to see how consuming 30 mL of vodka in between the readings affects it, as compared to a control group that will get 60 mL of water. How large should the sample size be to detect the same difference? Assume the within-group standard deviation is the same as in your pilot study.

Part Two: Randomization

For the next experiment, they want to compare regular beer 250 mL, light beer 250 mL, and nonalcoholic beer, and have asked you to randomize Islanders to one of these three treatments. It is known that gender and family history of alcohol impact how well a person can tolerate alcohol and respond to pain. You want to make sure that all three treatments are balanced (within reason) in each of these strata. The Investigators did their best to recruit as many males and females as possible for this study just to be sure that you had enough subjects. They also recorded whether an Islander had a family history of alcohol.

The number of Islanders that they were able to recruit was:

Female (id 1 to 42) – no family history of alcohol	n=42
Female (id 43 to 54) – family history of alcohol	n=12
Male (id 55 to 114) – no family history of alcohol	n=60
Male (id 115 to 138) – family history of alcohol	n=24

You already calculated the sample size needed for this project, now you need to assign treatments to the Islanders. Assume your sample size calculation recommended that you assign 36 Islanders to each treatment for a total of 108 Islanders. Create a stratified randomization that is ready to be used (“user friendly”) by an Investigator. You do not have to randomize all Islanders, but you do need to randomize enough Islanders to maintain the power of the study (n=108).

1. Place the final randomization in the second tab of your Excel file. List the Island id, the strata they are in, and the treatment that the Islander should receive. Your assignment will be graded on accuracy, completeness, and user friendliness.
2. Explain how to use the results posted in your Excel spreadsheet to an Investigator.
3. If your Investigators asked why the three treatments do not always occur consecutively, how would you respond to their question?