

## BS805 Fall 2022 Week 2

Be sure to follow the *Assessment Guideline 1: Writing up Homework* at the end of the syllabus in preparing the homework for submission.

Homework assignments need to be uploaded to the blackboard website by 2 PM on the due date.

In each homework report, be sure to include an introductory and a summary paragraph. Also, include the relevant parts of your SAS code where appropriate in your answer for each question.

A clinical trial was conducted to determine the effect of a drug for high blood pressure in obese individuals. Seventy subjects who were overweight and had high blood pressure were entered into the trial. All subjects were placed on a strict diet and exercise regimen; 35 subjects were randomly assigned to receive placebo, and the remainder received the study drug. The study was blinded, so subjects were not informed whether the drug that they received was the study drug or the placebo. Weight and systolic blood pressure were measured on all subjects at baseline, and again at the trial completion. We will use the change in systolic blood pressure as the outcome, and investigate the effect of the drug on this outcome. In addition to the effect of the drug, investigators wish to determine if subjects who were more compliant with the diet and exercise regimen lowered their blood pressure. The investigators have decided that a compliant subject was one who **lost at least 10 kilograms of weight**.

The data for these subjects is contained in the raw data file *hw2\_f2022\_blood.csv* on Blackboard Learn.

The variables are:

1. *id*
2. *drug* (0 = Placebo, 1 = Study Drug)
3. *systolic blood pressure* (mm Hg) at time 1 (baseline)
4. *weight* (in pounds) at time 1 (baseline)
5. *systolic blood pressure* (mm Hg) at time 2 (trial completion)
6. *weight* (in pounds) at time 2 (trial completion)

Weight at baseline ranges from 254.44 to 345.99 pounds. Weight at trial completion ranges from 228.48 to 328.86 pounds. Systolic blood pressure ranges from 152.77 to 173.90 mm Hg at baseline, and from 122.72 to 164.64 mm Hg at trial completion. Value specified here are rounded to the second decimal place, though note again that there should be four values after the decimal place for the measures of systolic blood pressure and weight in these data.

A) Correctly read in the data and create a saved SAS data set called “hw2\_saved”. In the data step, use arrays and looping to create two new variables that give the weights in kilograms (divide weight in pounds by 2.205), one for each time point. Also, for each subject, using arrays and looping, create two new variables for 1.) the change in weight (in kilograms) and 2.) the change in blood pressure for subjects. Also, create a new variable that records if the subject has been compliant with the diet and exercise regimen (1 if compliant, 0 if not compliant; be sure to format this variable). The compliance variable does not need to be made with an array.

B) In a **new and separate** program, use the saved SAS data set from part A with appropriate SAS procedures to test pair-wise associations among the four variables, drug, compliance, change in blood

pressure and change in weight- that is, separately analyze the associations between: drug and compliance; drug and change in blood pressure; drug and change in weight; compliance and change in blood pressure; compliance and change in weight; change in blood pressure and change in weight. These will require using the correct procedures according to the type of the variables in question (continuous and Gaussian, categorical). Be sure to state all hypotheses and results.

C) In the same program as in part B, perform two-factor ANOVA, first with interaction included and then, if justified, without interaction. Use the change in blood pressure as the outcome, with drug and compliance as the factors. Is the design balanced? Provide numeric evidence to support your conclusion regarding balance of the design. In each ANOVA, use 0.05 as the level of significance. Be sure to state all relevant hypotheses and the results of each of the statistical tests, as well as the mean outcome values for the factors, i.e., the two drugs and the two compliance groups, in the more appropriate model. Can we say that the study drug reduced blood pressure in this trial?

D) Compare results between part B and C, and then make comments on your findings.