

Your Name: _____

Names of people you worked with: _____

Task: Consider the Back Pain & Botox example from class. The randomized clinical trial examined whether the drug botulinum toxin A (Botox) is helpful for reducing pain among patients who suffer from chronic low back pain. The 31 subjects who participated in the study were randomly assigned to one of two treatment groups: 16 received a placebo of normal saline and the other 15 received the drug itself. The subjects' pain levels were evaluated at the beginning of the study and again after eight weeks. The researchers found that 2 of the 16 subjects who received the saline experienced a substantial reduction in pain, compared to 9 of the 15 subjects who received the actual drug.

Use playing cards to represent the data and to simulate a randomization test.

1. What is the null hypothesis in the study? Write it down in words and in symbols (parameters).
2. What does each playing card represent? How many cards are there?
3. What do the red and black colors of the cards represent? How many red and how many black cards do you have?
4. Please shuffle the cards. Which part of hypothesis testing does "shuffle the cards" correspond to?
5. What does dealing the cards into two groups represent? How many cards do you deal into each group?
6. How many of your Botox patients had pain reduction? Is the value you got more extreme than the observed data or less extreme than the observed data?
7. Shuffle and deal a few times. Report your values and whether the values are each more extreme or less extreme than the observed data.

Solution:

1. The null hypothesis is that Botox does not have any impact on back pain relief. In symbols, we write:

$$H_0 : p_{btx} = p_{pl}$$

where p is the true (population) probability of pain relief.

2. Each card represents a person, there are 31 cards, the same as the number of observations in the dataset.
3. The red cards are the individuals who have pain reductions. The black cards are the individuals who did not have pain reduction.
4. When you shuffle the cards you are breaking the connection between the treatment and the response. There will be no connection between the color of the card (the outcome) and the treatment. We are forcing the null hypothesis to be true. (Additionally, we are forcing the groups to be similar on all other confounding variables as well.)
5. Dealing the cards represents running the experiment (under the true null hypothesis setting). The group of size 15 are those who received Botox. The group of 16 are those who received the placebo. That is, randomly assign whether a person will get Botox, but do so under the setting that the Botox has no relationship with the pain relief.
6. I don't know what value you got, but most people in class should have gotten a result that was less extreme than the observed value of 9 Botox patients with pain relief.