Case 3: Evaluating a New Blood Pressure Medication (Sample Size Calculation)

A pharmaceutical company is developing a new blood pressure (BP) drug. They want to design a clinical trial to compare the effectiveness of their new drug with current standard treatment. The researchers hypothesize that the new drug will result in a greater reduction in systolic BP compared to standard treatment. The expected mean reduction in systolic BP with the new treatment is 12 mmHg, and the expected mean reduction in systolic BP with the standard treatment is 8 mmHg. The expected standard deviation of the reduction in systolic BP is 10 mmHg, and the minimum clinically significant difference is 4 mmHg. How many volunteers must be recruited to achieve at least 90% power of the study at a significance level of 2.5%?

Case:

Initial Questions

1. What are the research objectives?

2. What are the statistical questions?

3. What is the response variable, and what is the data type of the response variable?

4. What are the explanatory variables of interest?

5. Are there covariates?

6. What is the population of interest?

7. What is the subject, and what is the number of distinct subjects?

8. Are there subject-level data?

9. Are response variables dependent (repeated measures / clustered subjects)?

10. Are the subjects selected randomly?

11. Are the subjects randomly assigned to different groups?

Initial Thoughts

