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Section B

Methods of Randomization

The Randomized Trial

- We want to assign a group of subjects to one of two groups—**Treatment A or Treatment B**
 - How can we do this in a random manner?

The Randomized Trial

- Random assignment
 - Flip a coin
 - “Heads”—Tx A
 - “Tails”—Tx B
- Roll a six-sided die (from a pair of dice)
 - Even number—Tx A
 - Odd number—Tx B
- Table of random numbers
 - Practical statistics for medical research, Altman, table B13
- Computer generated random numbers
 - STATA

“Almost” Random Assignment

- Alphabetical
 - Tx A = patients with last name A-M
 - Tx B = patients with last name N-Z
- Telephone number/social security number
 - Tx A = last digit odd
 - Tx B = last digit even
- Sequential
 - Tx A = morning patients
 - Tx B = afternoon patients
- There are potential problems in the “almost random” assignment scheme—thoughts?

Simple Randomization (Flip a Coin)

- Randomize individuals to one of two treatments
 - If n is big, works great
- Randomize individuals to one of two treatments
 - If n is small there may be imbalance with respect to . . .
 - ▶ Sample sizes
 - ▶ Other variables

Potential Problems with Simple Randomization

- Unequal sample sizes
- If the study has a very small sample size, there is no guarantee that the two groups will have equal sample size using simple randomization
- Bad luck
 - Extremely unbalanced sample sizes
- Bad luck (worst case scenario)
 - All Tx A
 - None Tx B

Example of Block Size of Four

- Blocked randomization
 - Suppose we want to randomize a small number of patients to two groups
 - AABB
 - ABAB
 - ABBA
 - BABA
 - BAAB
 - BBAA

Example of Block Size of Four

- Roll a die (#1-6) to determine pattern
 - Each pattern has same probability of being chosen (one in six)
- Guarantees balance after every four patients

Example of Block Size of Four

- Example—suppose 12 subjects total
 - Roll die: you roll a “3”
 - “3” corresponds to ABBA
- Assignments for first four subjects
 - Subject # 1: group A
 - Subject # 2: group B
 - Subject # 3: group B
 - Subject # 4: group A

Blocked Randomization

- Altman, p. 87
 - You can have blocks of any size

Potential Problem with Simple Randomization

- Imbalance on a key variable
 - If study is very small, no guarantee groups are “comparable”
 - Solution—stratify
 - Suppose you are worried about differential age distributions in each group assigned
 - Stratify on age, then you do block randomization
 - Younger: ABBA BABA
 - Older : BBAA ABAB