BLOCKED RANDOMIZATION WITH RANDOMLY VARYING BLOCK SIZES

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Abstract: When planning a randomized clinical trial, careful consideration must be given to how participants are selected for various arms of a study. Selection and accidental bias may occur when participants are not assigned to study groups with equal probability. A simple random allocation scheme is a process by which each participant has equal likelihood of being assigned to treatment versus control groups. However, by chance an unequal number of individuals may be assigned to each arm of the study and thus decrease the power to detect statistically significant differences between groups. Block randomization is a commonly used technique in clinical trial design to eliminate bias and achieve balance in the allocation of participants to treatment arms, especially when the sample size is small. This method increases the probability that each arm will contain an equal number of individuals by sequencing participant assignments by block. Yet still, the allocation process may be predictable, for example, when the investigator is not blinded and the block size is fixed. In this paper, we provide an overview of blocked randomization and illustrate how to avoid selection bias by using randomly varying block sizes.

Key words: Blocked randomization, randomly varying block sizes, randomized clinical trial

Acknowledgements: This manuscript was made possible by a grant from NCMHD/NIH (P20MD002289) entitled “Teamwork in Research and Intervention to Alleviate Disparities Project (TRIAD).”