Randomization in Clinical Trials: a biostatistician task

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Introduction: Randomized clinical trials stand as the golden standard for evidence-based clinical investigation on humans, providing robust methodologies to evaluate new interventions (1). By employing stochastic processes to allocate participants to treatment and control groups, randomization minimizes bias and enhances the validity of results (1,2). This ensures unpredictability in treatment assignment, mitigating selection, response, and confounding biases, thus safeguarding the statistical integrity of the study (1,3,4). Various randomization techniques address specific trial needs (5). Simple randomization is the most straightforward, offering equal allocation probabilities but risking imbalance in small samples (6). Block randomization ensures numerical balance across groups but may fail to address covariate comparability (7). Stratified randomization improves group balance concerning key covariates but demands careful variable selection to prevent empty strata (5,6). Adaptive randomization adjusts allocation probabilities during the trial to manage imbalances but introduces complexity and potential predictability (1,8). Selecting the appropriate randomization method requires careful consideration of study design, sample size, and confounding factors to ensure reliable results (5). Beyond method selection, effective implementation is crucial, necessitating adherence to best practices outlined in the CONSORT 2010 guidelines (1). Proper documentation of allocation sequence generation, masking procedures, and protocol monitoring ensures reproducibility and integrity (1). This session will introduce randomization in clinical trials, present different methodologies, and explore their strengths and weaknesses.

Keywords: Clinical trials, Biostatistics, Randomization

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