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Is there really any benefit to stratified randomisation in practice ?

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Routes from India, currently working as a senior clinical data scientist with focus on programming in Boehringer ingelheim based in Ingelheim, germany and recently graduated with a Master of Science in Health Data Science from Univeristy of manchester, In my free time i like travelling, hiking, trekking and board games.

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“Randomized controlled trials (RCTs) are the gold standard for evaluating interventions in clinical research. Stratified randomization is a common technique used to balance prognostic factors across treatment groups, aiming to increase the precision of treatment effect estimates. However, its effectiveness and efficiency compared to simple randomization with covariate adjustment remain a subject of debate.

A simulation study as part of master’s thesis at university of Manchester was performed to compare the performance of stratified randomization and simple randomization with covariate adjustment under various conditions, including different sample sizes, association levels between covariates and outcomes, stratification levels, and treatment effects. By employing a linear regression model, key performance metrics such as type I error rate, standard error, bias, and coverage probability were assessed.

These findings suggest that stratified randomization can offer significant advantages, particularly in smaller sample sizes and when dealing with imbalanced strata. It demonstrated improved statistical power and reduced standard errors, leading to more precise estimation of treatment effects. However, the benefits were more pronounced in specific scenarios, highlighting the need for careful consideration of study design and analysis.”

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