



Dipartimento di Statistica e Metodi Quantitativi

***Casual Inference for Clinical Trails*:
A Spellchecker's Guide to Randomization Tests in
Complex Settings***

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Abstract

Sir Austin Bradford Hill, the developer of the first randomized clinical trial, was a proponent of simplicity in statistical analysis, and strongly emphasized careful study design as the critical component of all medical studies. While he didn't mention randomization tests in his 1937 book, I believe he would have liked their simplicity and interpretability. Any inference procedure which assumes random sampling from a population ignores Fisherian principles regarding the analysis of designed experiments. And clinical trials are the quintessential designed experiment. While we hear quite often about preservation of type I error rates and, more recently, about causal inference, these are natural elements of a randomization test. We discuss these issues and demonstrate that randomization tests can be used for more complex settings, such as multiple (>2) treatment comparisons, analyses with missing outcome data, and subgroup analyses. It is interesting to note that the only cohort of statisticians NOT excited about randomization tests in this age of causal inference are the designers and conductors of randomized clinical trials! I will conclude with a few historical notes about Fisher and de Finetti.

*The two most often misspelled words during my term as Biometrics co-editor.

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