

Francis I. Proctor Foundation Guide to Randomization and Masking

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Welcome!

This is a compendium and guide for best (esssential!) practices in trial randomization and masking.

Chapter 1

Randomization

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1.1 Introduction

Random allocation of treatment to units (individuals or clusters) is perhaps the single strongest design tool we have in epidemiology and clinical research to estimate the causal effect of a treatment on outcomes. Randomization ensures that individuals who receive treatment are, on average, exchangeable with those who do not (Altman and Bland, 1999). Without randomization, individuals who seek or receive treatment are almost inevitably different from those who do not, often in immeasurable ways. This leads to confounding of the treatment-outcome relationship.

Importantly (Altman and Bland, 1999):

“The term random does not mean the same as haphazard but has a precise technical meaning. By random allocation we mean that each patient has a known chance, usually an equal chance, of being given each treatment, but the treatment to be given cannot be predicted.”

References

Bibliography

Altman, D. G. and Bland, M. J. (1999). Treatment allocation in controlled trials: why randomise? *BMJ*, 318(7192):1209–1209.