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Multiple Imputation of missing values for randomized controlled trials: A step-by-step tutorial using mice

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Abstract

Concepual framework: Randomized Controlled Trials (RCTs) are a widely used research protocol in applied research. Among others, a major challenge of RCTs is the presence of missing data due to participant dropout. This leads to loss of power and estimation bias. Multiple imputation (MI) is becoming increasingly popular to deal with missing data in Randomized Controlled Trials. However, MI can produce biased results if not carried out properly. In addition, the required assumptions and steps to develop proper MI for RCTs can be challenging. There is a scarcity of practical guidelines to implement MI for such protocols.

Objectives: In this article we provide a step-by-step tutorial on (1) how to assess missing data in a RCT and how to avoid common misconceptions and pitfalls, (2) how to implement MI in and RCT using the mice package, (3) how to analyze RCT data in the MI framework such as implementing linear models, comparison of effect sizes, and plotting results, and (4) how to develop sensitivity analysis to assess robustness and impact of MI.

Sample: We illustrate this tutorial with a case RCT for wellbeing in social workers (N = 82) comparing two interventions (mindfulness-based intervention, and wellbeing-based intervention) across four measurements (pre intervention, post intervention, 2-month and 4-month follow-ups). Participants were mostly female (92.7%), single (46.3%) and with undergraduate studies (62.2%). Self-report measurements of depression, anxiety, and mindfulness are used as outcomes.

Implications: MI showed stability of the findings and tests used for this dataset, while also the strength of increasing power of conclusions. This tutorial can aid applied researchers to use MI with rigor in their RCT designs. Limitations and extensions of the field are also addressed

Keywords

tutorial; multiple imputation; RCTs; mice

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