Randomization-based Inference within principal strata

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In randomized studies, treatment comparisons conditional on intermediate post-randomization outcomes using standard analytic methods do not have a causal interpretation. An alternate approach entails treatment comparisons within principal strata defined by the potential outcomes for the intermediate outcome that would be observed under each treatment assignment. In this paper, we develop methods for randomization-based inference within principal strata. The proposed methods are compared with existing large sample methods as well as traditional intent-to-treat approaches. This research is motivated by HIV prevention studies where few infections are expected and inference is desired within the always-infected principal stratum, i.e., all individuals who would become infected regardless of randomization assignment.

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