

Trial Designs for Evaluating Combination HIV Prevention Approaches

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Abstract: Recent development of both biomedical and behavioral interventions provides the potential of maximize their population impact in risk reduction of HIV transmission via combination prevention intervention approaches. However, developing powerful and easy-to-implement clinical trial design(s) to assess the effectiveness of combined biomedical and behavioral interventions has been inadequate. We conduct Monte-Carlo simulation studies via the Cox proportional hazards models for time to incident HIV-transmissions to investigate four leading candidate trial designs: 1) single-factor design, 2) factorial design, 3) active-versus-control “multi-arm” design, and 4) all-versus-none “kitchen-sink” design, for assessing combination prevention intervention approaches. Their potential public health impact is also investigated. In this paper, we compare the pros and cons among the four designs, and argue that the factorial design is an efficient design particularly suitable for combination prevention intervention approaches when multiple candidate interventions are included.