

Design and Analysis of Group-Randomized Trials: A Review of Recent Practices

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We reviewed group-randomized trials (GRTs) published in the *American Journal of Public Health* and *Preventive Medicine* from 1998 through 2002 and estimated the proportion of GRTs that employ appropriate methods for design and analysis.

Of 60 articles, 9 (15.0%) reported evidence of using appropriate methods for sample size estimation. Of 59 articles in the analytic review, 27 (45.8%) reported at least 1 inappropriate analysis and 12 (20.3%) reported only inappropriate analyses. Nineteen (32.2%) reported analyses at an individual or subgroup level, ignoring group, or included group as a fixed effect.

Hence increased vigilance is needed to ensure that appropriate methods for GRTs are employed and that results based on inappropriate methods are not published. (*Am J Public Health*. 2004;94:393–399)

DURING THE PAST 25 YEARS, increased attention has been devoted to exploring the impact of intraclass correlation (ICC) in the design and analysis of group-randomized trials (GRTs) and to identifying appropriate methods for these trials. Despite this attention, periodic reviews of published GRTs have found that many investigators employed methods that do not account for the ICC properly.

A 1990 review of GRTs published in medical and epidemiological journals between 1979 and 1989¹ found that only 3 (19%) of the 16 reviewed articles accounted for ICC properly in sample size calculations, and only 8 (50%) accounted for ICC in the analysis. A meta-analysis of evaluations of 8 separate trials of a school-based program to

prevent drug use reported that only 2 (25%) accounted for ICC in the analysis.² Simpson et al.³ reviewed all GRTs published in the *American Journal of Public Health* and *Preventive Medicine* between 1990 and 1993; they reported that only 4 (19%) of 21 articles included power calculations and only 12 (57%) included analyses that took ICC into account. A more recent review of community health interventions⁴ included 8 GRTs; only 1 (12%) reported taking ICC into account properly in sample size calculations, though 7 (88%) accounted for ICC in the analysis.

In the meantime, methodologists have continued to focus attention on valid methods for estimating sample size and analyzing data from GRTs; a summary of

the work published in the last 5 years is provided in another article in this issue.⁵ However, no recent review of published GRTs has examined the effect of this increased attention on the practices of investigators who conduct GRTs.

It is important to continue to monitor the published literature to determine the impact of recent methodological developments. Such reviews enable methodologists to determine the extent to which issues of clustering are recognized among investigators and to identify areas that may need further attention. They also alert investigators to attend more closely to the issues that they are missing. The goals of this study were to review GRTs recently published in the *American Journal of Public Health* and *Preven-*

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