Pragmatic and Group-Randomized Trials in Public Health and Medicine

Website: https://prevention.nih.gov/grt

Suggested Activity: Part 2

NIH Office of Disease Prevention

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Reading Olson R, Wipfli B, Thompson SV, Elliot DL, Anger WK, Bodner T, Hammer LB,

Perrin NA. Weight Control Intervention for Truck Drivers: The SHIFT

Randomized Controlled Trial, United States. American Journal of Public Health.

2016:e1-e9.

Questions

The primary criteria for choosing a research question are 1) whether the trial will address an important public health question, and 2) whether there is preliminary evidence of feasibility and efficacy for the intervention. How would you evaluate this study with respect to those two criteria?

- The four primary threats to internal validity in a GRT are selection, differential history, differential maturation, and contamination. How would you evaluate this study with regard to those four threats to internal validity?
- One of the major threats to the statistical validity in a GRT is low power. The most important factors are the number of groups per condition and the expectations for the intraclass correlation and variance for the primary outcome. Did the investigators describe their power or sample size calculations for this study? Did they address these three factors?
- 4. What was the major design employed in this trial? Was it a single factor design? A cohort or cross-sectional design?
- 5. Was any effort made to ensure that the units of assignment would be balanced across study conditions with respect to potential confounding variables? Did the team employ a priori matching or stratification, or constrained randomization?.