

Answer Key to Suggested Activity Questions for Part 3

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

1. How many time intervals were included in the analysis for the primary outcome?

They included two time intervals in the analysis: “We included group assignment, time (baseline and 6 months), and the group-by-time interaction in the models, with drivers nested within terminals.

2. How would you characterize their approach to the analysis of the primary outcome? Did they use a mixed model? A randomization test? GEE? Another approach?

“Before conducting the main analyses, we explored differences in baseline characteristics between experimental groups by using generalized estimating equations to account for the nesting of drivers within terminals (i.e., each driver belonged to a terminal). We also examined differences in baseline characteristics between study completers and dropouts. We included variables on which groups differed at baseline, or that were associated with drop out, as covariates in the main analyses. We used generalized estimating equations for main analyses and we included all fully enrolled drivers as randomized.” So their approach was GEE, with regression adjustment for covariates.

3. Was the analysis approach appropriate for the design and the data? What are the implications for the results?

No. GEE is not appropriate given only 11 groups per condition without a small sample correction. There was no mention of a small sample correction in this paper. This means that the p-values may overstate the significance of the findings reported in this paper.

4. Explain their intent to treat analysis. Did they have measured outcome data for all enrolled participants at 6-months follow-up? How do you reconcile their report of an intent-to-treat analysis with their retention rate?

In the footnote to Figure 1, the authors report that “All participants who completed enrollment were included in analyses.” That is consistent with Figure 1 itself, which reports that 0 participants were excluded. At the same time, they did not have measured outcome data for all participants at 6-months follow-up, as they report in Figure 1 that only 275 of their 452 enrolled participants completed the 6-month follow-up. As such, they were missing outcome data for 40% of their enrolled sample. There was no mention in the paper of how they dealt with those missing data. For example, there was no mention of multiple imputation to replace missing data, or any other technique, e.g., last observation carried forward. As such, it is unclear how they performed an intent to treat analysis.