Pragmatic and Group-Randomized Trials in Public Health and Medicine

NIH Office of Disease Prevention Website: https://prevention.nih.gov/grt e-mail: GRT@mail.nih.gov

Answer Key to Suggested Activity Questions for Part 1

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. What was the primary research question of this trial?

"Primary hypotheses were that the intervention would be more effective than usual practice at producing (1) reductions in directly measured body weight and body mass index (BMI; defined as weight in kilograms divided by the square of height in meters), (2) improvements in self-reported dietary behaviors (fruit and vegetable intake, calories from fat, sugary food and drink consumption, fast-food consumption), and (3) improvements in self-reported physical activity."

2. What was the primary endpoint? How was it measured?

"We computed BMI from directly measured body weight (resolution 0.5 lb; Tanita TBF-310GS scale, Tanita Corporation, Tokyo, Japan) and height (nearest 1/8 inch; SECA 213 stadiometer, SECA, Hamburg, Germany). We verified scale calibration daily with a 25pound weight (11.34 kg). Drivers were weighed in work clothes after removing shoes, socks, belts, watches, and items from pockets."

3. What was the target population for the trial?

Truck drivers employed by US companies that "provide interstate transportation services and operate at least 2 larger terminals (about 80+ drivers each).

4. What were the units of assignment in this trial?

"The unit of randomization was a company terminal, which was defined as a companyowned facility with driver services or amenities beyond parking (e.g., drivers' lounge, laundry, maintenance)."

5. How were the units of assignment recruited and randomized?

"Researchers recruited companies through personal contacts, referrals, and phone calls... At each company, we selected an even number of terminals, matched in pairs by size (number of drivers), and then we randomized 1 terminal from each pair to the intervention condition and assigned the other to the control condition."

6. How many units of assignment were randomized to each condition?

"We evaluated intervention effectiveness with a cluster-randomized design involving 22 terminals from 5 companies in the United States in 2012 to 2014."

7. What were the units of observation in this trial?

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"Qualified drivers were mailed a survey and instructions for attending open enrollment periods at terminals."

8. How were the units of observation recruited?

"Interested drivers responded to advertisements and were screened for eligibility by phone. Qualified drivers were mailed a survey and instructions for attending open enrollment periods at terminals."

9. What were the eligibility criteria?

"Eligibility criteria included a BMI of at least 27, an interest in managing or losing weight, and no medical conditions prohibiting increased physical activity. The first and smallest company had an eligibility requirement of 9 months of job tenure. Tenure requirements were removed after the next 2 companies experienced lower-than-expected enrollment at their first terminals.

10. How many units of observation were measured in each unit of assignment?

"Ultimately, 452 drivers fully enrolled at baseline (86.9% of planned sample); 275 returned at 6 months (Figure 1)." With 22 terminals, this resulted in an average of 452/22=20.5 drivers per terminal at baseline and 12.5 drivers per terminal at 6 months.