ABSTRACT.

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Title: Generalizing Cluster Randomized Control Trial Results to a Target Population.

Background

Populations enrolled in trials are often selected under strict inclusion and exclusion criteria depending on the study designs, thus have different underlying characteristics than populations in clinical settings. In the presence of heterogeneity between participants in a randomized control trial and the target population where the treatment is intended to be applied, the population average treatment effect observed in the trial often leads to a biased quantification of the sample average treatment effect observed in clinical practice. The Bridging Income Generation with Group Integrated Care (BIGPIC) study was a cluster randomized trial for cardiovascular risk reduction that evaluated the impact of group medical visits and/or microfinance on blood pressure reduction. Findings from BIGPIC sub-group analysis showed that women, younger individuals, individuals without health insurance, and those with lower employment indices at baseline experienced greater systolic blood pressure (SBP) reductions in the microfinance (MF) and group medical visit-microfinance arms (GMV-MF) compared to those in the usual care (UC) arm. We intend to evaluate treatment effects for blood pressure reduction on a sample target population obtained from the Primary Health Integrated Care Project for Chronic Conditions (PIC4C) project.

Study Objectives

The study has two aims,

1. To assess the distribution of covariates that influence the treatment effects in the BIGPIC study and PIC4C sample population.
2. To generalize population average treatment effects from BIGPIC study to a sample population of the PIC4C project.

Methods

We implemented the BIGPIC trial eligibility criteria to select a sample of the PIC4C population that included adults greater than 35 years who had either diabetes or hypertension. We used standardized mean differences to assess differences in distribution of baseline characteristics between the two populations. We implemented inverse odds of trial participation weighting to extend inferences from the BIGPIC findings, obtained confidence intervals and adjusted for multiple comparisons using a Bonferroni correction.

Results

On average, BIGPIC participants were less likely to have health insurance, be male, be unemployed, and had lower monthly earnings. Compared with the UC arm, our transportability analyses in the PIC4C sample showed that the mean reduction in systolic blood pressure was 0.4 mm Hg lesser in the GMV-MF arm (95% CI, -4.9 to 5.8 mm Hg), 0.9 mm Hg greater in the GMV arm (95% CI, -6.2 to 4.4 mm Hg), and 0.9 mm Hg lesser in the MF arm (95% CI, -4.7 to 6.4 mm Hg). For comparison, the BIGPIC analysis estimated greater average SBP reduction of 3.9 mm Hg, 3.3 mm Hg, and 2.3 mm Hg in GMV-MF, GMV, and MF arms, respectively, compared to the usual care arm.

Conclusions

The estimated mean reduction in systolic blood pressure was smaller in the target population, compared with the BIGPIC study. The reduced point estimates of the treatment effect and increased uncertainties in the target population estimates compared to the BIGPIC study reflect the major differences in gender, age, occupation, monthly earnings, and comorbidities between the two populations.