**ABSTRACT.**

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

**Background:** The treatment effect observed in randomized controlled trials may not reflect the actual effect in the target population if the trial and target populations have differently distributed treatment effect modifiers. The Bridging Income Generation with Group Integrated Care (BIGPIC) study was a cluster randomized trial for cardiovascular risk reduction that assessed the effectiveness of group medical visits (GMVs) and/or microfinance (MF) relative to the Usual Care (UC) arms on blood pressure reduction. The study’s objective was to generalize the population average treatment effects from BIGPIC study to a sample target population obtained from the Primary Health Integrated Care Project for Chronic Conditions (PIC4C) project.

**Methods:** To compare the distribution of baseline characteristics between the two populations, standardized mean differences were utilized. A weighted linear mixed-effects model was employed on the BIGPIC data to analyze the primary and secondary outcomes, with inverse estimated odds of trial participation used as weights. We obtained confidence intervals and adjusted for multiple comparisons using a Bonferroni correction.

**Results:** BIGPIC participants were on average slightly younger, less likely to have health insurance, were less likely to be formally employed, and with lower monthly earning indices. Compared to the usual care arm, the transportability analyses showed an increase in estimated average systolic blood pressure of 0.2 mm Hg in the GMV-MF arm (98.3% CI, (-5.0 to 5.4 mm Hg); a reduction in estimated average systolic blood pressure of 0.6 mm Hg in the GMV arm (98.3% CI, -5.7 to 4.5 mm Hg), and an increase in estimated average systolic blood pressure of 0.3 mm Hg greater in the MF arm (98.3% CI, -5.1 to 5.6 mm Hg). Stability analysis suggested a lot of treatment effect modification.

**Conclusions:** The mean reduction in SBP, both for GMV-MF, GMV and MF relative to UC arms was attenuated in the target population compared to the estimates from the BIGPIC trial. When treatment effect modifiers are differentially distributed between the trial and the target populations, treatment effects estimated using the trial data are not directly interpretable in the context of the target population.