# Generalizing Cluster Randomized Control Trial Results to a Target Population

By

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***Abstract of Generalizing Cluster Randomized Control Trial Results to a Target Population, by Rophence Ojiambo, Degree ScM, Brown University, May 2023***

**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 microfinance (MF) relative to the Usual Care (UC) arms on blood pressure reduction.

**Objective:** To generalize the population average treatment effects from the 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:** The transportability analyses showed that compared to the UC arm, the mean reduction in systolic blood pressure was 0.2 mm Hg lesser in the GMV-MF arm (98.3% CI, -5.0 to 5.4 mm Hg), 0.6 mm Hg greater in the GMV arm (98.3% CI, -5.7 to 4.5 mm Hg), and 0.3 mm Hg lesser in the MF arm (98.3% CI, -5.1 to 5.6 mm Hg).

**Conclusion:** The attenuated point estimates of the treatment effect and increased uncertainties in the target population estimates compared to the BIGPIC study reflect the major differences in demographics and comorbidities between the two populations.

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# 1 Introduction

Randomized control trials (RCTs) are usually considered the gold standard for estimation of causal treatment effects. By randomizing treatment assignments, confounding is eliminated, which, under relatively mild conditions, ensures unbiased estimates of average treatment effect (ATE) in the population which underlies the sample used for estimation and yields strong internal validity. Cluster randomized controlled trials are becoming more common in the evaluation of interventions, especially in health services research [1,2]. These trials involve randomizing groups of participants to receive interventions instead of individual participants, which is useful when the intervention is applied at the cluster level (e.g., training, educational interventions, or broad media campaigns for health promotion). Cluster RCTs are also used when there is concern about contamination, where an individual's actions may influence the outcome for other participants leading to within cluster correlation [3].

Generalizability refers to extending trial results from the trial sample to a target population in which the study is nested (e.g., a study that is nested within a health care system), while transportability refers to extending trial results to a target population that is separate from the trial population. Concerns about generalizability in public health studies include the lack of representation (e.g., healthy volunteer bias and lack of representation of historically marginalized groups). As a result, when treatment effect modifiers, that is, variables that affect treatment efficacy, are differently distributed between the trial and target population the ATE calculated using trial participants is biased for the ATE in the target populations [4,5]. Recently, several statistical methods have been developed to generalize or transport treatment effects to a target population when only a sample of baseline covariates is available from the target population (i.e., no outcome or treatment information is available from the target population) [6–9].

Cardiovascular diseases (CVDs) account for over 30% of all deaths globally, with a rise in rates of CVD deaths observed in low- and middle-income countries (LMICs), while high income countries (HICs) have seen a decline in rates [10,11]. The major modifiable risk factors for CVDs include hypertension, diabetes, hyperlipidemia, smoking, and obesity [12]. LMICs face challenges in healthcare systems, such as insufficient health care expenditures, inefficient health care delivery systems, and limited health care workers especially in rural areas [13,14]. Incorporating social determinants of health and strategies such as microfinance and group medical visits into care delivery may be cost-effective and culturally appropriate ways to address these barriers [15].

Microfinance (MF) is a financial service tailored to serve the needs of low-income individuals or groups, such as money transfers, insurance, microcredits, or microloans, that can be integrated with healthcare initiatives to improve health outcomes and it has been studied in fields such as child health, infectious diseases, and women's health [16–19]. Group medical visits (GMVs), where healthcare clinicians meet with groups of patients with similar diseases, are a way to meet the rising demand for healthcare delivery for patients with chronic diseases. GMVs can encourage self-efficacy, social support systems, and improve the quality of patient-centered care [20].

The Bridging Income Generation with Group Integrated Care (BIGPIC) [15,21] 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 among people with either diabetes or hypertension or people who were at high risk of developing diabetes (elevated Leicester Risk Assessment score $\geq$ 7). 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 associated with MF and combined GMV plus MF compared to those receiving usual care (UC) (i.e., these variables are treatment effect modifiers).

In this thesis, we evaluate the transportability of BIGPIC results using a target population sample of baseline covariate data obtained from the Primary Health Integrated Care Project for Chronic Conditions (PIC4C) [22] project using electronic health records from the Academic Model Providing Access to Healthcare (AMPATH), Kenya.

# 2 Generalizability of Randomized Control Trials

## 2.1 Populations

The concept of population representativeness and generalizability of trial results are closely related (Figure 1). First, the target population is the population to whom the study intervention results are intended to be interpreted with respect to. A target sample refers to a sample representative of the target population. The trial population is the group of individuals eligible for the trial defined by the enrollment process and inclusion or exclusion criteria. The resulting study sample refers to participants enrolled in the clinical trial. Lastly, the analysis sample is the group of people from the study sample that is used to estimate the treatment effect. Loss to follow up, dropout, and other complicating factors such as cross-over can lead to the analysis sample being different than the study sample and well-established methods can be used to estimate treatment effects in the context of the study population. Stuart et al. [8,23] defines the sample average treatment effect (SATE) as the average treatment effect in the study sample underlying the trial and the ultimate interest is the treatment effect across all subjects in the population, that is, the population average treatment effect (PATE). Lack of generalizability refers to differences in treatment effects between the study population and the target population.

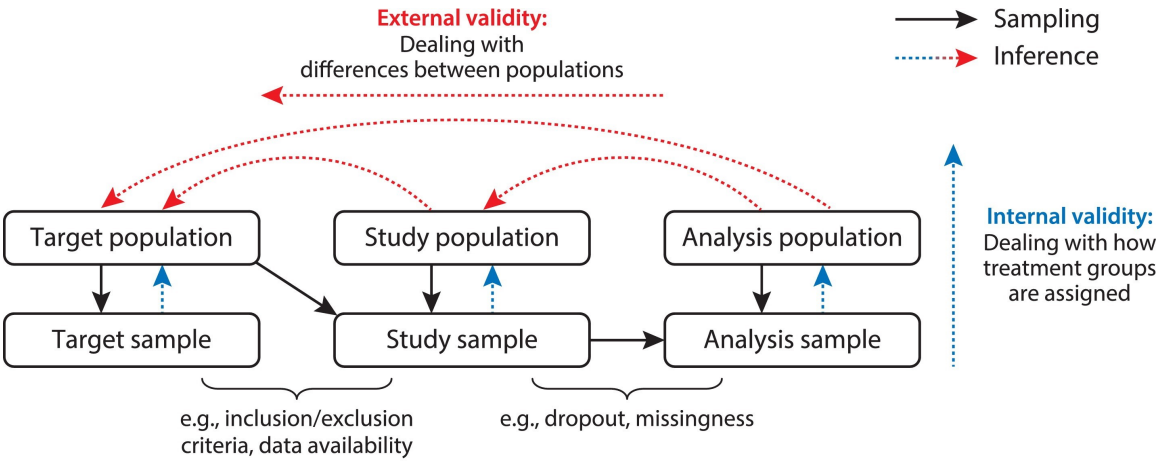


Figure 1: Target, study, and analysis populations in relation to internal and external validity [24].

## 2.2 Assessing distribution of baseline Covariates

It is important to assess the similarities or differences between the study and target populations prior to generalizing existing study results. When only baseline covariates account for relevant study and target population differences, Greenhouse et al. [25] suggested the use of multiplicity-adjusted univariate tests to test for difference in distribution of treatment effect modifiers between the trial population and the target population. The authors proposed a methodological framework to determine generalizability of RCTs results that included the identification of data sources, data sub-setting based on demographic variables to facilitate comparisons to a target population, measuring the outcome and performing sensitivity analyses.

Tipton [26] proposed a generalizability index that uses the trial participation probabilities to capture differences among all observed covariates simultaneously for the trial and target population data. Tipton's generalizability index does not require distributional assumptions, and visually quantifies the similarities between the two distributions, hence referred to as "histogram distance." The index is bounded between 0 and 1. A value of 0 indicates distinct

differences between the samples of the trial and target populations, whereas a value of 1 signifies that the trial sample is likely a representative sample from the target population. Thus, an index score < 0.5 has been used to suggest low generalizability whereas scores > 0.9 indicate remarkably high generalizability [26].

Alternatively, generalizability can be assessed by calculating the absolute standardized mean difference (ASMD) of each covariate $\frac{|\bar{X}_{study}-\bar{X}|}{\sigma_{\bar{X}}}$, where $\bar{X}_{study}$ and $\bar{X}$ are the average of baseline covariates in the study and target populations, respectively, and $\sigma_{\bar{X}}$ is the standard deviation of $\bar{X}$ [27]. Greater differences between the covariate distribution in the trial and target populations are represented by larger ASMD values whereas smaller ASMD indicate similarities between the trial and target population [28]. However, while this approach reveals covariate-by-covariate differences, it does not assess the joint distribution of covariates. Stuart et al. [8] proposed the use of propensity scores to compare the joint distributions of covariates.

## 2.3 Review of Methods for Estimating Average Treatment Effects in the Target Population

There are several approaches for estimating the treatment effect in the target population based on either the probability of trial participation to equate the samples of the trial and target populations, or on outcome models used to predict outcomes in the target population, or on a combination of both. The probabilities of trial participation conditional on baseline covariates can be estimated using standard methods for estimating conditional probabilities.

### 2.3.1 Inverse probability of sampling weighted (IPSW) estimator

Generalizing estimates from RCTs to a target population often uses weighting to adjust for differences between the study population and the target population. Cole and Stuart [4]

used logistic regression models to estimate the conditional probabilities of trial participation and then employed inverse probability of selection weights to generalize inferences from a randomized clinical trial to a specified target population. Simulations showed that for the heterogeneous intent-to-treat effect scenario, the conventional estimates of the hazard ratio were severely biased with poor coverage of confidence intervals; however, the proposed inverse probability weighted estimator was unbiased with confidence intervals that had close to the nominal coverage [4].

Stuart et al. [8 ] used a propensity score (logistic regression) model to match, weight and sub-classify the outcomes among the controls to a target population given the set of baseline covariates and summarize the differences between the trial sample and target population. The propensity scores were then used to assess generalizability by using methods such as inverse probability of treatment weighting (IPTW) to make the control group appear like the target population. Each control subject was assigned their own weight and the target population was stratified according to the sampling score distribution. Predicted outcomes under control were then compared to the outcomes observed in the population [8].

Buchanan et al. [9] considered IPSW estimator for generalizing two different Adult Clinical Trials Group (ACTG) randomized clinical trials of Human Immunodeficiency Virus (HIV) treatment to two different target populations, namely all women currently living with HIV in the United States (US) and all people living with HIV in the US. To generalize the observed difference in average change in Cluster of Differentiation 4 (CD4) cell count from baseline between treatment arms among women in the trials to the target populations, the study employed the use of IPSW and stratified estimators to estimate the ATE in the target populations. A summary of the results suggested that the ACTG trial results were more generalizable for US men with HIV than US women with HIV [9].

### 2.3.2 Outcome Model Based Approach

Outcome regression modeling approaches estimate average treatment effects by fitting outcomes regression using the trial data, ATEs are then obtained by marginalizing over the covariate distribution of target population (predicting counterfactuals for the target population) [29]. The outcome model can be implemented using standard parametric approaches such as generalized linear regression models.

### 2.3.3 Combination of weighting and outcome modeling approaches

Doubly robust methods for transportability and generalizability combine models for trial participation and outcome regression approaches and are consistent when at least one of the models is correctly specified. If both regression functions are consistently estimated, the doubly robust methods are asymptotically efficient [24]. Another advantage is that it allows for more data adaptive (e.g., machine learning) methods to estimate the outcome model and the model for study participation while still allowing for valid inference.

A Targeted Maximum Likelihood Estimation (TMLE) is a method that combines both weighting and outcome modeling strategies. TMLE models both the trial participation and outcome using pre-treatment baseline covariates and is doubly robust [30,31]. The outcome model is then used to predict outcomes in both the trial and target population data under treatment conditions, which are then offset by a function of trial participation probabilities and then used to estimate the average treatment effect in the target population. Several other doubly robust estimators for transportability resemble the IPSW estimator but use alternate approaches to propensity scores to derive sampling weights [32,33].

# 3 Methods

## 3.1 Notation, Assumptions and Causal Effects

Suppose investigators are interested in generalizing a cluster randomized trial of N participants to a well-defined target population; $N_j$ is defined as the sample size of the $j^{th}$ cluster and individuals in cluster $j$ are indexed by $i \in 1, \cdots, N_j$. $S$ is defined as an indicator of trial membership with $S_i = 1$ indicating that individual *i* is in the trial while $S_i = 0$ indicating individual *i* is in the target population. We assume that the trial and the target populations are non-nested. Let *Y* denote the individual-level outcome of interest, $X$ a vector of measured baseline covariates, $A_j$ denote the cluster-level treatment assignment; we only consider finite sets of possible treatments, which we denote by $\mathcal{A}$, we let $Y_{ij}(1)$ denote the potential individual-level outcome for individual *i* under treatment in cluster *j*, and $Y_{ij}(0)$ denote the potential outcome for individual *i* in cluster *j* under control. Additionally, we define the average cluster level observed outcome in cluster *j* as $\bar{Y_j} = \frac{1}{N_j} \sum_{i=1}^{N_j} Y_{ij}$.

### 3.1.1 Causal quantities

Here, we let $Y_{ij}(a)$ be the potential outcome for individual i in cluster j under treatment assignment $a \in \mathcal{A}$ such that the average potential outcome in cluster $j$ is defined as, $\bar{Y_j}(a) = \frac{1}{N_j} \sum_{i=1}^{N_j} Y_{ij}(a)$ [29]. Our main causal quantity of interest is the average potential outcome in the target population, defined as $E\big[\bar{Y}(a) \,\big|S = 0\big] = E\Big[\frac{1}{N_j} \sum_{i=1}^{N_j} Y_{ij}(a)\Big]$. The average potential outcome in the target population will be different from the average potential outcome in the cluster randomized trial population when treatment effect modifiers are distributed differently in the cluster randomized trial and in the target population, that is when $E[\bar{Y}(a) \mid S = 0] \neq E[\bar{Y}(a) \mid S = 1]$ [29].

### 3.1.2 Assumptions

Several assumptions are required when estimating $E[\bar{Y}(a)]$ using data from an RCT and target population.

1. Positivity of trial participation conditional on baseline covariates; all individuals in the target population have non-zero probability of participating in the trial: $Pr[S = 1|X = x] > 0$, for every *x* with positive density in the target population.

2. Positivity of treatment assignment; conditional on the covariates, there is positive probability of being assigned to each of the treatment interventions being compared in the RCT data: $Pr[A = a|X = x, S = 1] > 0$ for each $a$ and $x$ with positive joint density in the trial.

3. Consistency of expected cluster outcomes, that is, for cluster *j* who received treatment $a$, the observed cluster outcome equals that cluster counterfactual outcome under the same treatment; that is, if $A_j = a,\ then\ Y_j = Y_j(a)$, for clusters $j \in 1, \cdots, m$, and every $a \in \mathcal{A}$.

4. Conditional exchangeability in the trial over A; in the trial, the potential mean outcome at the cluster level under treatment a is independent of treatment conditional on baseline covariates, that is, $\bar{Y}(a)\ \perp\ A|\ X, S = 1$.

5. Conditional exchangeability over S; conditional on baseline covariates, the potential mean outcome at the cluster level is independent of population (trial or target population), that is, $\bar{Y}(a)\ \perp\ S\ |X$.

### 3.1.3 Identification

Under the above assumptions, the average potential outcome in the target population can be identified using the observed data as;

$$\mathrm{E}[\mathrm{Y(a)}|\mathrm{S}=0] = \mathrm{E}\Big[\mathrm{E}[\bar{\mathrm{Y}}|\mathrm{X},\ \mathrm{S}=1,\ \mathrm{A}=\mathrm{a}]\Big] \tag{1}$$

The average treatment effects comparing treatment interventions $a\ and\ a'$ in the target population can also be identified by the following equation;

$$\mathrm{E}\Big[\mathrm{E}[\bar{\mathrm{Y}}|\mathrm{X},\mathrm{S}=1,\mathrm{A}=\mathrm{a}]\ \Big|\ \mathrm{S}=0\Big] - \mathrm{E}\Big[\mathrm{E}[\bar{\mathrm{Y}}|\mathrm{X},\mathrm{S}=1,\mathrm{A}=\mathrm{a}']\Big|\mathrm{S}=0\Big] \tag{2}$$

The identifiability result suggests doing the analysis at the cluster level, but as the BIGPIC trial only involves a few clusters such analysis is not feasible.

### 3.1.4 Estimation and inference

We consider the inverse odds of trial participation weighting to extend inferences from cluster randomized trial participants to the target population. The inverse odds of trial participation probability is defined as $\frac{P[S=0|X]}{P[S=1|X]}$. The inverse odds of trial participation probability can provide insight into how much the study sample represents the target population. If the study sample has similar characteristics and demographics as the target population, then the inverse odds of trial participation probability will be a constant. We implement the analysis of transporting the BIGPIC trial results to the target population using mixed effects models with a random effect of cluster that are weighted by the inverse-odds of trial participation.

### 3.1.5 Data sources

The Chronic Disease Management (CDM) Program was formed by the Academic Model Providing Access to Healthcare (AMPATH) in Eldoret, Kenya in partnership with local communities and the Kenyan government in response to the growing burden of CVDs [34]. AMPATH has also created a comprehensive microfinance group care model that has been extended to patients with diabetes and hypertension. The implementation of this contextualized care delivery model has contributed to statistically significant improvements in blood pressure reduction and linkage to retention in care [35]. The study data was accessed through Brown University while the target population data was obtained from the community screening of the PIC4C study participants. Both data come from Western Kenya among new patients and those known to have chronic conditions, and receiving care within the CDM network.

**BIGPIC:** The BIGPIC study was a four-arm cluster randomized trial for cardiovascular risk reduction comparing; (1) usual clinical care (UC), (2) usual clinical care plus microfinance groups (MF), (3) group medical visits (GMVs) and (4) group medical visits integrated into microfinance groups (GMV-MF). The primary outcome of interest was a one-year change in systolic blood pressure (SBP). Key secondary outcomes measured in the study included change in diastolic blood pressure (DBP) and one-year change in the overall CVD event risk as measured by the QResearch-based QRISK3 score [15].

The study was conducted within the AMPATH catchment area in Western Kenya in four counties; Busia, Kisumu, Uasin Gishu and Trans Nzoia. To be eligible for the trial, participants had to be aged 35 years or older, in the CDM program, and had diabetes (fasting glucose $\geq$ 7 mmol/L) or were at increased risk for developing diabetes (impaired fasting glucose) with fasting glucose 5.6 to 6.9 mmol/L or elevated Leicester Risk Assessment score ($\geq$ 7). All participants had either diabetes or hypertension (SBP $\geq$ 140 MM Hg or DBP $\geq$ 90 mm Hg).

Participants were excluded if they had acute illness, were terminally ill, were pregnant, had HIV or if they were unable to provide informed consent. The study had 24 clusters with the health facility catchment area as the clustering unit, and randomization was stratified to ensure balance by county, type of health facility, and level of pre-existing microfinance participation. The study's prespecified subgroup analysis included assessing the change in SBP in the following groups: sex, age, baseline monthly earnings, baseline wealth category, baseline health insurance, baseline livestock ownership, recruitment pathway and baseline land ownership. The study data was collected during study visits at baseline, 3 months and at 12 months. The full details of the study design and methods are available elsewhere [21].

**PIC4C:** Built upon existing AMPATH HIV care model and making use of the gains made such as infrastructure, technology, and human capital; PIC4C was an initiative that was implemented in 2018 as a partnership between the Kenyan Ministry of Health, Moi Teaching & Referral Hospital, the World Bank, and the Access Accelerated Initiative (AAI). The PIC4C model includes early diagnosis of individuals with diabetes, hypertension, breast and/or cervical cancer at the primary level of service providers, and structured referrals to higher level service providers for confirmation of diagnosis and treatment initiation. The PIC4C model ensures retention of patients in care through monitoring and evaluation. The project pilot study implementation began in Busia and Trans Nzoia counties and aimed to link patients to care with voluntary chronic care benefit package operated by the National Hospital Insurance Fund (NHIF) for affordable health care financing [22].

We implemented the BIGPIC trial eligibility criteria as closely as possible in the PIC4C to select a sample of the PIC4C population that would be eligible for BIGPIC (avoiding violations of the positivity of trial participation assumption); henceforth, for brevity, we refer to this population as the "target population". We applied the BIGPIC inclusion criteria of age, diabetes, or hypertension to the PIC4C sample. Other BIGPIC eligibility criteria such as information on HIV status, increased risk of developing diabetes (elevated Leicester score $\geq$ 7) was not captured in the PIC4C data, and we did not implement this to select

the target population sample. The target population lacked covariate information on total cholesterol levels, LDL cholesterol, QRISK3 score, International wealth Index, Livestock and Land ownership.

To create a combined dataset that included covariate, treatment, and outcome information, we added the sample data from PIC4C to that from BIGPIC. The resulting dataset contained covariate information only from PIC4C and covariate, treatment, and outcome information from BIGPIC. Our goal was to compare the covariate distribution between the BIGPIC study and the target population from PIC4C and to extend inferences from the BIGPIC study to the target population. We mapped as many covariates as possible from the target population to the BIGPIC study, such as demographic characteristics (age, gender, body mass index, monthly earnings, occupation status, education level, and NHIF status) and comorbidities (diabetes and hypertension). The main outcome of interest was the change in SBP, while the secondary outcome of interest was the change in DBP.

### 3.1.6 Statistical Analysis

***Descriptive statistics and comparisons between populations:*** We computed descriptive statistics for all covariates in both the BIGPIC study and the target population and utilized standardized mean differences to compare the two populations. This was done before and after weighting the participants in the BIGPIC study. An absolute standardized mean difference (SMD) exceeding 0.20 is generally considered a threshold indicating a meaningful imbalance in the covariate distribution between two populations. This is because an SMD of 0.20 corresponds to a 20% difference in the means of the covariate between the two groups. A large imbalance in covariate distribution between two groups can lead to biased estimates of treatment effects and limit the generalizability of study findings. Therefore, researchers typically aim to achieve balance in the covariate distribution between study groups by using appropriate study designs, randomization procedures, and statistical methods [36].

***Estimating mean change sin SBP/DBP and comparing between treatment groups:*** To estimate the 1-year absolute mean change in SBP and DBP, we employed linear mixed-effects models that accounted for the clustering of individuals within the health facility catchment area by using random effects. We fitted separate models for primary, secondary analysis and the subgroup analyses. The models included baseline covariates such as the baseline value of the outcome, baseline cluster-specific mean of the outcome, gender, recruitment pathway, type of health facility (sub-county hospital, health center, or dispensary), age, and amount of pre-trial MF activity in the cluster.

To extend inferences on the mean changes in SBP/DBP from BIGPIC to the target population, we employed inverse odds of trial participation weighting techniques to upweight participants who were more likely to belong to the target population. A logistic regression model was used to predict the probability of trial participation and the predicted probabilities used to calculate the inverse odds of trial participation for each BIGPIC participant. Finally, we employed a weighted linear mixed-effects models to the BIGPIC data for the primary and secondary outcomes, adjusting for all the previously mentioned baseline covariates with weights equal to the inverse of the estimated odds of trial participation.

# 4 Results

## 4.1 Transportability Results

Our main analyses used data from 2890 BIGPIC participants (708 assigned to UC arm, 709 to MF, 740 to GMV, and 733 to GMV-MF) and 911 individuals sampled from the PIC4C who met the BIGPIC eligibility criteria. Women represented 69.9% and 54.7% of the BIGPIC and PIC4C data, respectively. Figure 2 shows the process of identifying our target population for our analyses.

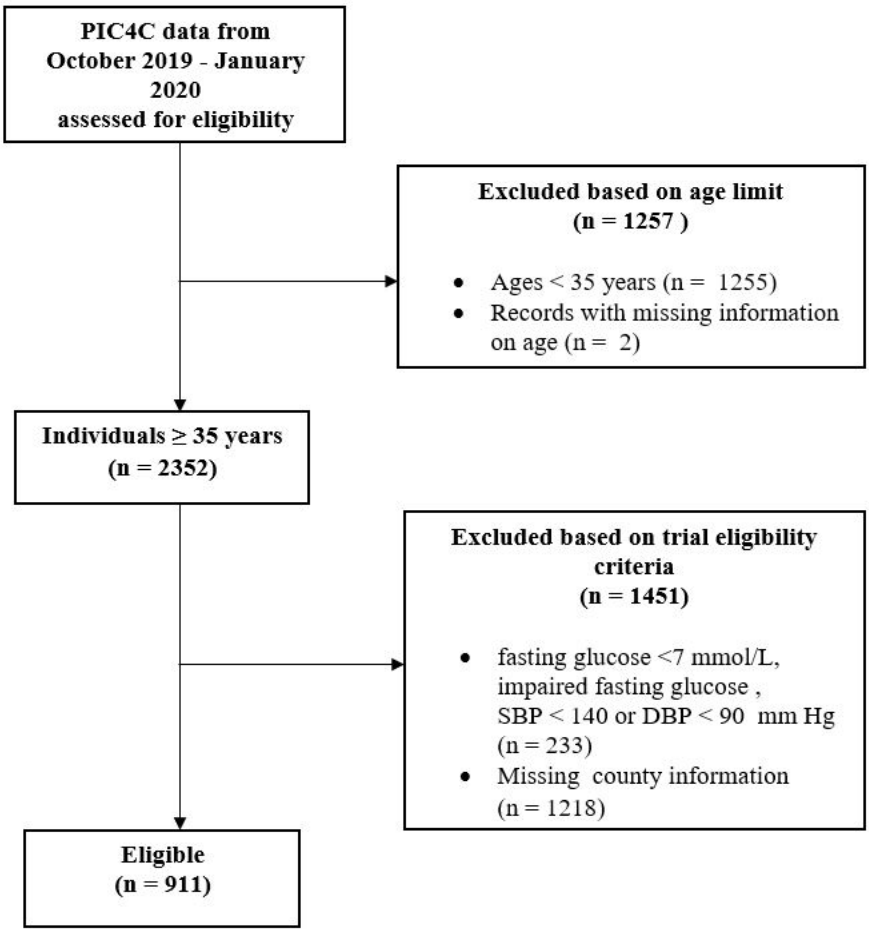


Figure 2: Flow diagram for identifying the target population sample in the PIC4C study

Table 1 presents descriptive characteristics for trial participants and the target population; Table 6 in the appendix shows descriptive characteristics for BIGIC trial participants stratified by treatment arm, while Table 7 shows descriptive characteristics for target population stratified by county. We found that BIGPIC participants were on average slightly younger, less likely to have health insurance, were less likely to be formally employed, with lower monthly earning indices, and had more diagnosed comorbidities (diabetes and hypertension). Several characteristics including age, sex, diabetes, hypertension, occupation, monthly earnings, education, and NHIF status were very imbalanced (standardized mean difference > 0.2) between BIGPIC participants and the target population.

Figure 3 shows standardized mean differences before and after weighting the BIGPIC participants by the inverse odds of trial participation, using a fully adjusted model to evaluate covariate balance. In Figure 3, the Unadjusted method refers to the BIGPIC only analysis and the Weighted method is the analysis adjusted for all covariates in the probability of trial participation model. For categorical variables, the average of all possible SMD are shown. We found the absolute standardized mean difference of all covariates after weighting is small (below 0.2).

Table 1: Baseline characteristics in the target populations and BIGPIC study.

| | Analysis Populations | | | |
|---|---|---|---|---|
| | Overall | Target Population | Study Population | SMD |
| **N** | **3801** | **911** | **2890** | |
| **County Demographics** | | | | |
| **County (%)** | | | | **0.192** |
| Busia/Vihiga | 1863 (49.0) | 464 (50.9) | 1399 (48.4) | |
| Kisumu/Siaya | 469 (12.3) | 148 (16.2) | 321 (11.1) | |
| Trans-Nzoia/Uasin Gishu | 1469 (38.6) | 299 (32.8) | 1170 (40.5) | |
| **Health Facility** | | | | **0.297** |
| Dispensary | 1158 (30.5) | 269 (29.7) | 889 (30.8) | |
| County/Sub-county | 1358 (35.8) | 412 (45.5) | 946 (32.7) | |
| Health Center | 1280 (33.7) | 225 (24.8) | 1055 (36.5) | |
| **Health Demographics** | | | | |
| **Age Group** | | | | **0.301** |
| 35-54 | 1316 (34.6) | 403 (44.2) | 913 (31.6) | |
| 55-74 | 2031 (53.4) | 443 (48.6) | 1588 (54.9) | |
| ≥75 | 454 (11.9) | 65 ( 7.1) | 389 (13.5) | |
| Female | 2518 (66.2) | 498 (54.7) | 2020 (69.9) | **0.318** |
| Body Mass Index (BMI) | 25.30 (5.69) | 25.37 (6.30) | 25.28 (5.48) | **0.015** |
| Diabetes | 664 (17.5) | 57 ( 6.3) | 607 (21.1) | **0.441** |
| Hypertension | 3444 (90.7) | 746 (81.9) | 2698 (93.5) | **0.357** |
| Baseline SBP, mmHG | 155.65 (20.57) | 149.89 (23.71) | 157.47 (19.11) | **0.352** |
| Baseline DBP, mmHG | 92.63 (12.04) | 93.01 (12.89) | 92.52 (11.76) | **0.040** |

| | | | | |
|---|---|---|---|---|
| **Lifestyle Demographics/Health Insurance** | | | | |
| **Occupation** | | | | **1.834** |
| Unemployed | 1870 (51.4) | 32 ( 4.3) | 1838 (63.6) | |
| Agribusiness | 1128 (31.0) | 546 (72.8) | 582 (20.2) | |
| Casual | 242 ( 6.7) | 116 (15.5) | 126 ( 4.4) | |
| Govt employee | 89 ( 2.4) | 29 ( 3.9) | 60 ( 2.1) | |
| Other | 309 ( 8.5) | 27 ( 3.6) | 282 ( 9.8) | |
| **Monthly Earnings** | | | | **1.680** |
| Not formally employed | 1897 (52.2) | 32 ( 4.3) | 1865 (64.7) | |
| Kshs <5,000 | 1166 (32.1) | 420 (56.0) | 746 (25.9) | |
| Kshs 5,000-10,000 | 276 ( 7.6) | 138 (18.4) | 138 ( 4.8) | |
| Kshs >10,000 | 294 ( 8.1) | 160 (21.3) | 134 ( 4.6) | |
| **Education level** | | | | **0.249** |
| No formal | 329 ( 8.7) | 129 (14.2) | 200 ( 6.9) | |
| Primary | 2273 (59.8) | 489 (53.7) | 1784 (61.8) | |
| Secondary+ | 1197 (31.5) | 293 (32.2) | 904 (31.3) | |
| NHIF Status | 714 (19.6) | 225 (29.8) | 489 (16.9) | **0.307** |

Table 1 shows counts with percentages in parenthesis, with abbreviations: N = number of individuals, NHIF = National Health Insurance Fund, SMD = standardized mean difference prior to statistical analysis. If there is more than one contrast, the average of all possible SMD are shown. Study population refers to BIGPIC study while target population refers to sample from PIC4C population.

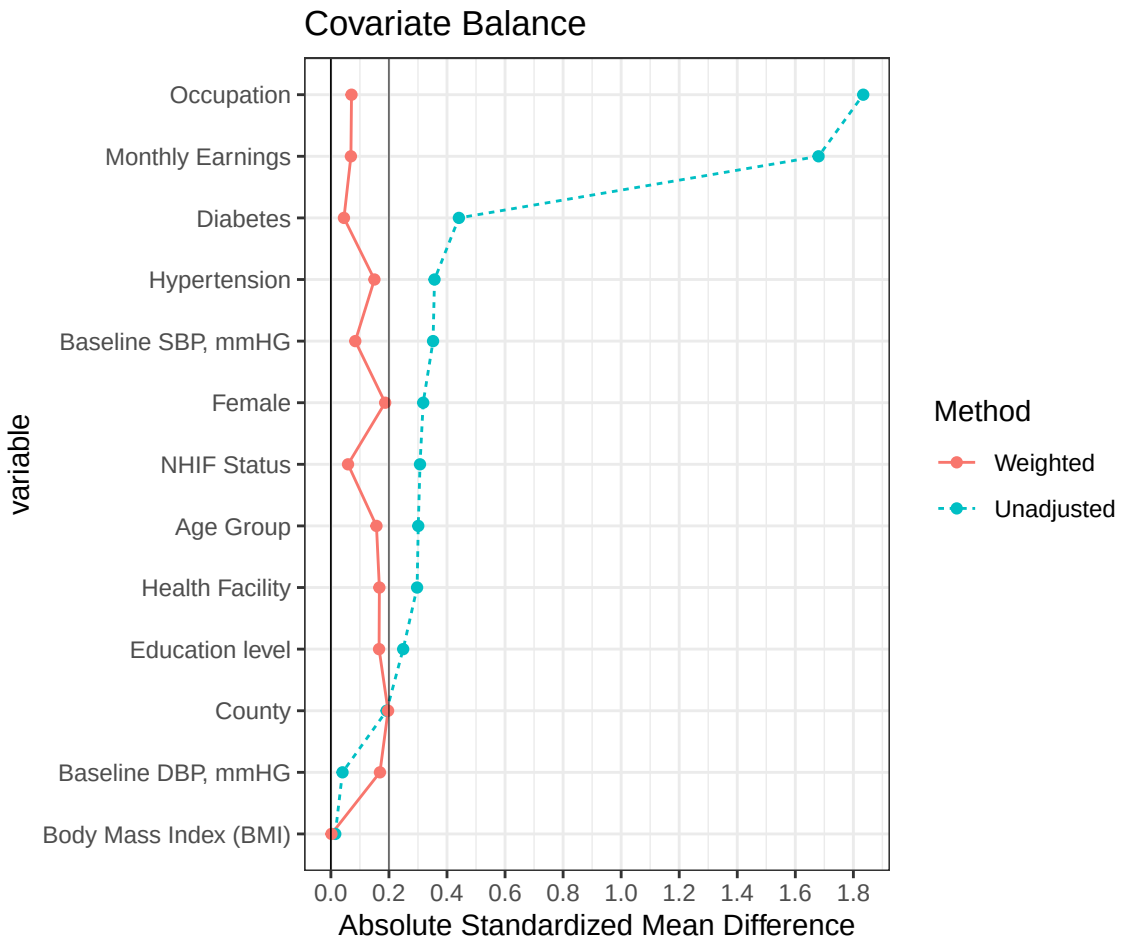


Figure 3: Absolute standardized mean differences comparing the BIGPIC study and target population before and after weighting to account for differences in baseline characteristics; Abbreviations: SBP = Systolic Blood Pressure, DBP = Diastolic Blood Pressure, NHIF = National Health Insurance Fund

Table 2 shows the estimates of the average change in SBP in the MF, GMV and GMV-MF, and their comparisons in the BIGPIC study and the target population. For all statistical adjustments, the estimated mean reductions in SBP were lower in the target population, compared to those in the BIGPIC trial. The 98.3% confidence intervals for the model-based estimates were adjusted for multiple comparisons using a Bonferroni correction. Compared with the UC arm, our transportability analyses in the target population showed that the mean reduction in systolic blood pressure was 0.2 mm Hg lesser in the GMV-MF arm (98.3% CI, -5.0 to 5.4 mm Hg), 0.6 mm Hg greater in the GMV arm (98.3% CI, -5.7 to 4.5 mm Hg), and 0.3 mm Hg lesser in the MF arm (98.3% CI, -5.1 to 5.6 mm Hg).

For comparison, the BIGPIC analysis estimated greater average SBP reduction of 3.9 mm Hg (98.3% CI, -8.5 to 0.7 mm Hg), 3.3 mm Hg (98.3% CI, -7.8 to 1.2 mm Hg), and 2.3 mm Hg (98.3% CI, -7.0 to 2.4 mm Hg) in GMV-MF, GMV, and MF arms, respectively, compared to the usual care arm [15].

Table 2: Results for BIGPIC study vs transportability analysis

| | **BIGPIC Study** | | | **Target Population** | | |
|---|---|---|---|---|---|---|
| | **UCMF-UC** | **GMV-UC** | **GMVMF-UC** | **UCMF-UC** | **GMV-UC** | **GMVMF-UC** |
| sbp change 3m | -3.25 (-7.97, 1.46) | -3.24 (-7.75, 1.26) | -1.01 (-5.64, 3.63) | -2.80 (-8.15, 2.55) | -6.56 (-11.65, -1.46) | -5.00 (-10.20, 0.21) |
| sbp change 12m | -2.31 (-7.02, 2.40) | -3.29 (-7.80, 1.21) | -3.91 (-8.53, 0.72) | 0.25 (-5.09, 5.60) | -0.64 (-5.73, 4.46) | 0.16 (-5.04, 5.37) |
| dbp change 3m | -3.34 (-5.41, -1.27) | -1.66 (-3.76, 0.45) | -1.36 (-3.50, 0.79) | -1.94 (-4.46, 0.58) | -1.52 (-4.02, 0.98) | -1.17 (-3.73, 1.39) |
| dbp change 12m | -2.35 (-4.42, -0.27) | -1.64 (-3.74, 0.47) | -3.25 (-5.40, -1.11) | -2.60 (-5.11, -0.08) | -1.84 (-4.34, 0.66) | -2.16 (-4.72, 0.40) |

Results for the unadjusted model (model with just an interaction term for time and treatment arm) showed that in comparison to the UC arm, the mean reduction in systolic blood pressure was 1.5 mm Hg greater in the GMV-MF arm (98.3% CI, -6.6 to 3.7 mm Hg), 0.3 mm Hg greater in the GMV arm (98.3% CI, -5.5 to 4.9 mm Hg), and 1.7 mm Hg greater in the MF arm (98.3% CI, -6.9 to 3.6 mm Hg), see the unadjusted model results in Table 8 in the appendix. Analyses adjusted for missing baseline covariates in the target population produced equivalent results to the complete case analyses, see Tables 19 - 22 in the appendix.

Similarly, Table 2 also shows the results for the secondary outcome in the target population showed that the mean reduction in diastolic blood pressure was 2.2 mm Hg greater in the GMV-MF arm (98.3% CI, -4.7 to 0.4 mm Hg), 1.8 mm Hg greater in the GMV arm (98.3% CI, -4.3 to 0.7 mm Hg), and 2.6 mm Hg greater in the MF arm (98.3% CI, -5.1 to -0.1 mm Hg), compared with the UC arm. For comparison, the BIGPIC analysis estimated greater average DBP reduction of 3.3 mm Hg (98.3% CI, -5.4 to 1.1 mm Hg), 1.6 mm Hg (98.3% CI, -3.7 to 0.5 mm Hg), and 2.4 mm Hg (98.3% CI, -4.4 to -0.3 mm Hg) in GMV-MF, GMV, and MF arms, respectively, compared to the usual care arm.

Sub-group analysis in the BIGPIC study showed that compared to the usual care arm, women experienced greater SBP reductions than men: -4.7 mm Hg (98.3% CI, -8.8 to -0.6 mm Hg), -4.0 mm Hg (98.3% CI, -8.0 to -0.0 mm Hg), and -3.3 mm Hg (98.3% CI, -7.5 to 0.8 mm Hg) in GMV-MF, GMV, and MF arms, respectively. Younger individuals experienced greater SBP reductions than older individuals in the GMV-MF and GMV arms. Additionally, individuals with lower employment and monthly earnings experienced greater SBP reductions in the GMV-MF and MF arms while those without health insurance at baseline experienced greater SBP reductions in the GMV-MF and GMV arms, see results in Tables 9 - 13 in the appendix.

## 4.2 Sensitivity analysis

We conducted a sensitivity analysis for our transportability analysis. Tables 3 - 5 present the results from the sensitivity analysis, where the Adjusted model refers to the weighted linear mixed effects that adjusted for all previously mentioned baseline covariates when estimating mean changes in SBP/DBP across treatment arms, while the Unadjusted model refers to the weighted linear mixed effects that only included an interaction term of time and the treatment arm. Here, we focus on the results from the adjusted models.

Without adjusting for occupation in our propensity score regression model, compared with the UC arm, the mean reduction in systolic blood pressure in the target population was 0.7 mm Hg greater in the GMV-MF arm (98.3% CI, -5.7 to 4.3 mm Hg), 1.9 mm Hg greater in the GMV arm (98.3% CI, -6.8 to 2.9 mm Hg), and 0.1 mm Hg greater in the MF arm (98.3% CI, -5.2 to 5.0 mm Hg), see Table 3.

Without adjusting for monthly earnings in our propensity score regression model, compared with the UC arm, the mean reduction in systolic blood pressure in the target population was 0.5 mm Hg greater in the GMV-MF arm (98.3% CI, -5.6 to 4.7 mm Hg), 2.2 mm Hg greater in the GMV arm (98.3% CI, -7.3 to 2.9 mm Hg), and 0.2 mm Hg greater in the MF arm (98.3% CI, -5.5 to 5.2 mm Hg), see Table 4.

On the other hand, without adjusting for both occupation and monthly earnings in our propensity score regression model, compared with the UC arm, the mean reduction in systolic blood pressure in the target population was relatively similar to that in the BIGPIC study in the GMV-MF arm, that is 3.11 mm Hg greater in the GMV-MF arm (98.3% CI, -7.8 to 1.6 mm Hg), and slightly greater in GMV and MF arms compared to the estimates in the BIGPIC study; 3.5 mm Hg (98.3% CI, -8.2 to 1.1 mm Hg), and 3.2 mm Hg (98.3% CI, -7.98 to 1.6 mm Hg) respectively, see Table 4.

Table 3: Weighted results: Adjusting for Occupation

| | Adjusted Model | | | Unadjusted Model | | |
|---|---|---|---|---|---|---|
| | **UCMF-UC** | **GMV-UC** | **GMVMF-UC** | **UCMF-UC** | **GMV-UC** | **GMVMF-UC** |
| sbp change 3m | -2.96 (-8.10, 2.17) | -5.67 (-10.53, -0.80) | -3.51 (-8.49, 1.47) | -4.69 (-9.77, 0.39) | -5.36 (-10.37, -0.36) | -5.38 (-10.38, -0.38) |
| sbp change 12m | -0.09 (-5.22, 5.04) | -1.94 (-6.80, 2.92) | -0.73 (-5.70, 4.25) | -1.87 (-6.95, 3.21) | -1.67 (-6.67, 3.33) | -2.63 (-7.62, 2.37) |
| dbp change 3m | -2.75 (-5.20, -0.30) | -2.14 (-4.57, 0.29) | -1.16 (-3.63, 1.32) | -2.72 (-5.27, -0.17) | -2.46 (-4.93, 0.02) | -1.77 (-4.26, 0.71) |
| dbp change 12m | -2.19 (-4.63, 0.26) | -1.67 (-4.10, 0.76) | -2.09 (-4.57, 0.38) | -2.20 (-4.75, 0.34) | -2.00 (-4.47, 0.47) | -2.73 (-5.22, -0.25) |

Table 4: Weighted results: Adjusting for Monthly earnings

| | Adjusted Model | | | Unadjusted Model | | |
|---|---|---|---|---|---|---|
| | **UCMF-UC** | **GMV-UC** | **GMVMF-UC** | **UCMF-UC** | **GMV-UC** | **GMVMF-UC** |
| sbp change 3m | -4.41 (-9.76, 0.94) | -4.35 (-9.44, 0.74) | -4.23 (-9.39, 0.93) | -6.30 (-11.58, -1.03) | -4.64 (-9.82, 0.54) | -6.04 (-11.19, -0.89) |
| sbp change 12m | -0.17 (-5.51, 5.18) | -2.23 (-7.33, 2.86) | -0.45 (-5.60, 4.71) | -2.12 (-7.39, 3.15) | -2.56 (-7.74, 2.62) | -2.29 (-7.44, 2.86) |
| dbp change 3m | -2.78 (-5.63, 0.06) | -1.18 (-4.01, 1.65) | -1.28 (-4.13, 1.56) | -3.13 (-6.01, -0.26) | -2.08 (-4.88, 0.72) | -2.35 (-5.14, 0.43) |
| dbp change 12m | -2.51 (-5.35, 0.33) | -2.05 (-4.88, 0.78) | -1.81 (-4.65, 1.04) | -2.88 (-5.76, -0.01) | -2.94 (-5.74, -0.14) | -2.88 (-5.67, -0.10) |

Table 5: Weighted results: Adjusting for both Occupation and Monthly earnings

| | Adjusted Model | | | Unadjusted Model | | |
|---|---|---|---|---|---|---|
| | **UCMF-UC** | **GMV-UC** | **GMVMF-UC** | **UCMF-UC** | **GMV-UC** | **GMVMF-UC** |
| sbp change 3m | -2.08 (-6.87, 2.71) | -3.60 (-8.21, 1.02) | -1.41 (-6.14, 3.33) | -3.09 (-8.21, 2.02) | -3.89 (-9.04, 1.27) | -2.73 (-7.90, 2.43) |
| sbp change 12m | -3.19 (-7.98, 1.60) | -3.55 (-8.16, 1.06) | -3.11 (-7.84, 1.62) | -4.29 (-9.41, 0.82) | -3.93 (-9.08, 1.23) | -4.49 (-9.65, 0.67) |
| dbp change 3m | -3.10 (-5.41, -0.80) | -1.97 (-4.36, 0.41) | -1.08 (-3.50, 1.34) | -2.80 (-5.21, -0.40) | -2.37 (-4.80, 0.06) | -1.76 (-4.20, 0.69) |
| dbp change 12m | -2.81 (-5.12, -0.51) | -2.31 (-4.68, 0.07) | -2.84 (-5.26, -0.43) | -2.55 (-4.96, -0.15) | -2.69 (-5.12, -0.26) | -3.54 (-5.98, -1.10) |

Transportability results from weighted sub-group analyses are shown in Tables 14 - 18 in the Appendix.

# 5 Discussion

We described methods for extending inferences from RCTs to a well-defined target population. Our main contribution is to show how recent work on transportability and generalizability methods can be applied to extend inferences from a cluster randomized trial. We estimated that mean reduction in SBP, both for GMV-MF, GMV and MF treatment arms, would be attenuated in the target population compared to the estimates from the BIGPIC trial.

Our results were consistent with positive impact on DBP reduction in the GMV-MF and MF arms compared to the UC in the target population. However, the DBP estimates in the target population were slightly reduced for the GMV-MF arm and slightly higher for the MF arm compared to the BIGPIC findings.

Our reduced point estimates of the treatment effect were less precise, particularly when we tried to fully adjust for the baseline covariate differences between the BIGPIC study and the target population. The increased uncertainty in the target population estimates compared to the BIPIC study was due to significant differences in gender, age, occupation, monthly earnings, and comorbidities between the two populations.

Sensitivity analyses for occupation and monthly earnings, the two covariates with the largest baseline differences between the BIPIC trial and the target population, showed results that were consistent with the BIGPIC findings, with a slightly higher beneficial impact in the GMV and MF arms. Similarly, sub-group analysis for the weighted model showed higher treatment effects among unemployed participants and those with lower monthly earning indices in the target population.

Our results need to be interpreted in view of several limitations, first our target population that met the inclusion and exclusion criteria for the BIGPIC trial had a sample size of $n = 911$, with some missing information on occupation, NHIF status, and health facility (17.8%, 17.0% and 0.55% respectively). Additionally, the target population lacked information on HIV status, and as such our target population could have included individuals with HIV whereas the BIGPIC trial was restricted to non-HIV adults. Therefore, our analyses can only account for variables that were measured in both the BIGPIC study and the target population, and those included in the propensity scores logistic regression model for the probability of trial participation that requires the model to be correctly specified.

Secondly, we used all variables common to the BIGPIC trial and target population measured at baseline. As seen from Table 1, the BIGPIC trial differed from the target population in terms of demographics, baseline characteristics, and other relevant factors that could influence the treatment effect. For example, the BIGPIC study had more females, most participants lacked NHIF and were not formally employed with lower monthly earnings. When fitting the propensity score model, the lack of participants in specific counties in the

trial and target populations resulted in merging of Busia/Vihiga, Kisumu/Siaya, and Trans-Nzoia/Uasin Gishu counties respectively. Similarly, differences in types of health facilities in the trial and target populations led to the merging of County/Sub-County health facilities, hence this could have resulted in loss of information.

The occupation and monthly earning variables were categorized differently in the two populations based on their screening and enrollment questionnaires. In the PIC4C community questionnaire form, participants were asked about their work history and benefits, and their past and recent work fell into various categories such as government employee, non-government employee, self-employed business, self-employed agriculture, non-paid volunteer work, student, homemaker, retired, unemployed (able to work), unemployed (unable to work), and casual laborers. The income was recorded as the average earnings of the household in Kenyan shillings (Kshs), received weekly, monthly, or yearly, and was grouped into different categories based on monthly income, such as less than Kshs $5,000$, $5,000-10,000$, $10,001-20,000$, $20,001-30,000$, $30,001-50,000$, $50,001-100,000$, and more than $100,000$.

In contrast, the BIGPIC study measured work productivity by asking participants about their primary job, which included categories such as farmer, business person, public sector employee, casual labor, temporal work, and other categories. Monthly incomes were measured per individual and grouped into various categories such as less than Kshs $1000$, $1000-2999$, $3000-4999$, $5000-9,999$, $10000-19,999$, $20,000-29,999$, $30,000-39,999$, and more than $40,000$. The occupation and monthly earnings variables had to further be categorized into fewer levels common to both populations when fitting the propensity score model, and this could have resulted in loss of information.

Third, our results varied across different specifications, suggesting that model specification and unmeasured variables would change our conclusions. Therefore, it is important to consider the inverse odds of trial participation probability when designing and interpret-

ing clinical trials, and to take steps to ensure that the trial population is as representative as possible of the target population. This may involve targeted recruitment strategies or inclusion criteria that prioritize individuals more representative of the broader population. Fourth, since the BIGPIC study involved randomization at the cluster level that can result in variation in the cluster effects, the magnitude of the cluster effects may be different in the target population compared to the BIGPIC population, which can influence the overall treatment effect in the target population.

Fifth, we lacked baseline covariate information on lipids, international wealth index, QRISK3 score, livestock, and land ownership in the target population. In contrast, the BIGPIC trial had access to many observed characteristics, including adherence, recruitment pathways, land ownership, and lipids information. As a result, our statistical adjustments for the propensity score model for inverse odds of trial participation weighting were limited to baseline characteristics that were observed in both the BIGPIC and target population. This highlights the need for population-level datasets that are of high quality to enable comprehensive characterization of potential target populations.

In conclusion, we present a formal discussion of external validity of interventions such as GMVs and MF that incorporate social health determinants into health care delivery for chronic diseases to improve cardiovascular health outcomes, particularly for sub-group of patients. We found that the BIGPIC results were more generalizable to younger individuals, those not formally employed or unemployed, those without health insurance, and with lower monthly earnings. While RCTs yield unbiased estimates of treatment effects in the study sample underlying the trial, they may not be sufficient for decision and policy makers who are interested in treatment effects in the target populations where the interventions are to be applied. Current methods and study designs have limitations in estimating treatment effects in a target population. The findings of this study underscore the need for more discussions on this issue and emphasize the importance of researchers paying attention to the challenges of generalizing treatment effects from a sample to a target population.

# Appendix

## A.1 Baseline characteristics of BIGPIC and target populations.

Table 6: Baseline Characteristics of the BIGPIC study Participants

| | | Total | UC | UC+MF | GMV | GMV+MF |
|---|---|---|---|---|---|---|
| **N** | | 2890 | 708 | 709 | 740 | 733 |
| **Sex** | Female | 2020 (69.9) | 522 (73.7) | 481 (67.8) | 510 (68.9) | 507 (69.2) |
| | Male | 870 (30.1) | 186 (26.3) | 228 (32.2) | 230 (31.1) | 226 (30.8) |
| **Age, yrs** | | 60.69 (12.15) | 59.78 (11.51) | 59.28 (12.91) | 62.12 (12.20) | 61.50 (11.72) |
| **Diabetes (self-reported or elevated blood glucose)** | No | 2275 (78.9) | 518 (73.2) | 589 (83.1) | 578 (78.4) | 590 (81.0) |
| | Yes | 607 (21.1) | 190 (26.8) | 120 (16.9) | 159 (21.6) | 138 (19.0) |
| **Baseline SBP, mm Hg** | | 157.47 (19.11) | 155.40 (19.88) | 158.95 (18.75) | 156.44 (17.53) | 159.10 (20.01) |
| **Baseline DBP, mm Hg** | | 92.52 (11.76) | 91.15 (11.87) | 92.29 (11.27) | 92.81 (11.11) | 93.76 (12.58) |
| **Hypertension** | No (SBP <140 mm Hg or DBP <90 mm Hg) | 189 ( 6.5) | 71 (10.0) | 41 ( 5.8) | 40 ( 5.4) | 37 ( 5.1) |
| | Yes (SBP ≥140 mm Hg or DBP ≥90 mm Hg) | 2698 (93.5) | 637 (90.0) | 668 (94.2) | 700 (94.6) | 693 (94.9) |
| **Total cholesterol** | <5.17 mmol/l | 2367 (84.3) | 568 (82.4) | 594 (85.2) | 594 (83.0) | 611 (86.4) |
| | ≥5.17 mmol/l | 442 (15.7) | 121 (17.6) | 103 (14.8) | 122 (17.0) | 96 (13.6) |
| **LDL cholesterol** | <4.14 mmol/l | 2585 (97.1) | 624 (96.0) | 655 (97.3) | 668 (97.5) | 638 (97.4) |
| | ≥4.14 mmol/l | 78 ( 2.9) | 26 ( 4.0) | 18 ( 2.7) | 17 ( 2.5) | 17 ( 2.6) |
| **QRISK3 score** | <10% | 1542 (55.0) | 373 (54.2) | 417 (59.8) | 376 (52.6) | 376 (53.3) |
| | 10%-19.9% | 851 (30.3) | 236 (34.3) | 187 (26.8) | 215 (30.1) | 213 (30.2) |
| | ≥20% | 413 (14.7) | 79 (11.5) | 93 (13.3) | 124 (17.3) | 117 (16.6) |
| **National Hospital Insurance Fund (NHIF)** | No | 2400 (83.1) | 576 (81.4) | 594 (83.8) | 618 (83.5) | 612 (83.6) |
| | Yes | 489 (16.9) | 132 (18.6) | 115 (16.2) | 122 (16.5) | 120 (16.4) |
| **Monthly earnings*** | Not formally employed | 1838 (63.7) | 483 (68.4) | 491 (69.3) | 423 (57.2) | 441 (60.3) |
| | Kshs <1,000 | 315 (10.9) | 43 ( 6.1) | 48 ( 6.8) | 120 (16.2) | 104 (14.2) |
| | Kshs 1,000-2,999 | 252 ( 8.7) | 55 ( 7.8) | 48 ( 6.8) | 79 (10.7) | 70 ( 9.6) |
| | Kshs 3,000-4,999 | 179 ( 6.2) | 42 ( 5.9) | 51 ( 7.2) | 47 ( 6.4) | 39 ( 5.3) |
| | Kshs ≥5,000 | 272 ( 9.4) | 74 (10.5) | 67 ( 9.4) | 65 ( 8.8) | 66 ( 9.0) |
| | Do not know | 27 ( 0.9) | 8 ( 1.1) | 4 ( 0.6) | 5 ( 0.7) | 10 ( 1.4) |
| | Refused | 3 ( 0.1) | 1 ( 0.1) | 0 ( 0.0) | 1 ( 0.1) | 1 ( 0.1) |
| **International Wealth Index** | ≤15.00 | 583 (20.2) | 118 (16.7) | 164 (23.1) | 154 (20.8) | 147 (20.1) |
| | 15.01-24.99 | 781 (27.0) | 163 (23.0) | 200 (28.2) | 221 (29.9) | 197 (26.9) |
| | 25.00-39.99 | 820 (28.4) | 227 (32.1) | 185 (26.1) | 193 (26.1) | 215 (29.4) |
| | ≥40 | 704 (24.4) | 200 (28.2) | 160 (22.6) | 172 (23.2) | 172 (23.5) |
| **Livestock** | No | 1010 (35.0) | 266 (37.6) | 266 (37.6) | 253 (34.3) | 225 (30.8) |
| | Yes | 1873 (65.0) | 441 (62.4) | 441 (62.4) | 485 (65.7) | 506 (69.2) |
| **Land ownership, acres** | 0 | 527 (19.8) | 161 (24.8) | 158 (24.2) | 113 (16.9) | 95 (13.8) |
| | 1 | 672 (25.3) | 180 (27.7) | 162 (24.8) | 155 (23.2) | 175 (25.5) |
| | 2 | 488 (18.4) | 124 (19.1) | 119 (18.2) | 102 (15.2) | 143 (20.8) |
| | 3 | 310 (11.7) | 67 (10.3) | 72 (11.0) | 81 (12.1) | 90 (13.1) |
| | 4 | 169 ( 6.4) | 32 ( 4.9) | 34 ( 5.2) | 48 ( 7.2) | 55 ( 8.0) |
| | ≥5 | 493 (18.5) | 85 (13.1) | 109 (16.7) | 170 (25.4) | 129 (18.8) |

[a] Values are n (%) or Mean (SD); UC = usual care; UC+MF = usual care plus microfinance; GMV = group medical visit; GMV+MF = group medical visit integrated into microfinance; DBP = Diastolic Blood Pressure; SBP = Systolic Blood Pressure; *100 Kenyan shillings (Kshs) = 1 U.S. dollar

Table 7: Baseline Characteristics of target population from PIC4C study

| | | Total | Busia | Siaya | Trans-Nzoia | Vihiga | p |
|---|---|---|---|---|---|---|---|
| **N** | | 911 | 218 | 148 | 299 | 246 | |
| **Health Facility** | County | 80 ( 8.8) | 55 (25.8) | 6 ( 4.1) | 3 ( 1.0) | 16 ( 6.5) | <0.001 |
| | Dispensary | 269 (29.7) | 60 (28.2) | 41 (27.7) | 80 (26.8) | 88 (35.8) | |
| | Health Center | 225 (24.8) | 29 (13.6) | 35 (23.6) | 86 (28.8) | 75 (30.5) | |
| | Sub County | 332 (36.6) | 69 (32.4) | 66 (44.6) | 130 (43.5) | 67 (27.2) | |
| **Sex** | Female | 498 (54.7) | 109 (50.0) | 82 (55.4) | 151 (50.5) | 156 (63.4) | 0.009 |
| | Male | 413 (45.3) | 109 (50.0) | 66 (44.6) | 148 (49.5) | 90 (36.6) | |
| **Age, yrs** | | 56.44 (12.06) | 56.64 (13.70) | 55.16 (9.12) | 57.76 (13.97) | 55.43 (9.08) | 0.070 |
| **Diabetes status** | No | 854 (93.7) | 203 (93.1) | 136 (91.9) | 284 (95.0) | 231 (93.9) | 0.614 |
| | Yes | 57 ( 6.3) | 15 ( 6.9) | 12 ( 8.1) | 15 ( 5.0) | 15 ( 6.1) | |
| **Baseline SBP, mm Hg** | | 149.89 (23.71) | 150.17 (26.71) | 144.24 (22.79) | 151.93 (20.97) | 150.57 (24.19) | 0.012 |
| **Baseline DBP, mm Hg** | | 93.01 (12.89) | 93.00 (12.88) | 89.72 (12.26) | 93.99 (12.35) | 93.82 (13.66) | 0.006 |
| **Hypertension** | No (SBP <140 mm Hg or DBP <90 mm Hg) | 165 (18.1) | 35 (16.1) | 49 (33.1) | 27 ( 9.0) | 54 (22.0) | <0.001 |
| | Yes (SBP ≥140 mm Hg or DBP ≥90 mm Hg) | 746 (81.9) | 183 (83.9) | 99 (66.9) | 272 (91.0) | 192 (78.0) | |
| **Blood pressure drugs** | No | 165 (37.9) | 43 (41.0) | 25 (34.2) | 63 (48.5) | 34 (26.8) | 0.003 |
| | Yes | 270 (62.1) | 62 (59.0) | 48 (65.8) | 67 (51.5) | 93 (73.2) | |
| **Diabetes drugs** | No | 405 (86.7) | 98 (84.5) | 64 (86.5) | 125 (89.3) | 118 (86.1) | 0.717 |
| | Yes | 62 (13.3) | 18 (15.5) | 10 (13.5) | 15 (10.7) | 19 (13.9) | |
| **National Hospital Insurance Fund (NHIF)** | No | 531 (70.2) | 120 (65.6) | 72 (64.9) | 195 (74.1) | 144 (72.4) | 0.122 |
| | Yes | 225 (29.8) | 63 (34.4) | 39 (35.1) | 68 (25.9) | 55 (27.6) | |
| **Monthly earnings*** | Not formally employed | 32 ( 4.3) | 7 ( 3.9) | 3 ( 2.7) | 12 ( 4.6) | 10 ( 5.0) | 0.070 |
| | Kshs <5,000 | 420 (56.0) | 90 (50.6) | 63 (55.8) | 145 (55.8) | 122 (61.3) | |
| | Kshs 5,000-10,000 | 138 (18.4) | 43 (24.2) | 13 (11.5) | 47 (18.1) | 35 (17.6) | |
| | Kshs >10,000 | 160 (21.3) | 38 (21.3) | 34 (30.1) | 56 (21.5) | 32 (16.1) | |
| **Body Mass Index (BMI)** | | 25.37 (6.30) | 24.91 (5.29) | 25.35 (6.55) | 25.50 (7.02) | 25.63 (6.06) | 0.642 |
| **Education** | No formal | 129 (14.2) | 35 (16.1) | 14 ( 9.5) | 56 (18.7) | 24 ( 9.8) | <0.001 |
| | Incomplete Primary | 323 (35.5) | 91 (41.7) | 48 (32.4) | 111 (37.1) | 73 (29.7) | |
| | Complete Primary | 166 (18.2) | 21 ( 9.6) | 43 (29.1) | 52 (17.4) | 50 (20.3) | |
| | Secondary+ | 293 (32.2) | 71 (32.6) | 43 (29.1) | 80 (26.8) | 99 (40.2) | |
| **Occupation** | Unemployed | 32 ( 4.3) | 7 ( 3.9) | 3 ( 2.7) | 12 ( 4.6) | 10 ( 5.0) | <0.001 |
| | Casual | 116 (15.5) | 11 ( 6.2) | 18 (15.9) | 33 (12.7) | 54 (27.1) | |
| | Agribusiness | 546 (72.8) | 147 (82.6) | 79 (69.9) | 198 (76.2) | 122 (61.3) | |
| | Govt employee | 29 ( 3.9) | 5 ( 2.8) | 7 ( 6.2) | 10 ( 3.8) | 7 ( 3.5) | |
| | NGO | 27 ( 3.6) | 8 ( 4.5) | 6 ( 5.3) | 7 ( 2.7) | 6 ( 3.0) | |

[a] Values are n (%) or Mean (SD); Abbreviations: DBP = Diastolic Blood Pressure, SBP = Systolic Blood Pressure, *100 Kenyan shillings (Kshs) = 1 U.S. dollar, Govt = Government, NGO = Non-Governmental Organization, +Secondary education and beyond

## A.2 Transportability results

Table 8: Weighted models for transportability analysis

| | Adjusted Model | | | Unadjusted Model | | |
|---|---|---|---|---|---|---|
| | UCMF-UC | GMV-UC | GMVMF-UC | UCMF-UC | GMV-UC | GMVMF-UC |
| sbp change 3m | -2.80 (-8.15, 2.55) | -6.56 (-11.65, -1.46) | -5.00 (-10.20, 0.21) | -4.65 (-9.94, 0.63) | -6.15 (-11.34, -0.97) | -6.61 (-11.80, -1.42) |
| sbp change 12m | 0.25 (-5.09, 5.60) | -0.64 (-5.73, 4.46) | 0.16 (-5.04, 5.37) | -1.66 (-6.94, 3.62) | -0.26 (-5.45, 4.92) | -1.45 (-6.63, 3.74) |
| dbp change 3m | -1.94 (-4.46, 0.58) | -1.52 (-4.02, 0.98) | -1.17 (-3.73, 1.39) | -2.20 (-4.90, 0.50) | -2.12 (-4.74, 0.50) | -2.21 (-4.84, 0.42) |
| dbp change 12m | -2.60 (-5.11, -0.08) | -1.84 (-4.34, 0.66) | -2.16 (-4.72, 0.40) | -2.91 (-5.61, -0.22) | -2.45 (-5.07, 0.16) | -3.21 (-5.84, -0.58) |

## A.3 BIGPIC sub-group analysis

Table 9: Sub-group analysis for gender

| Gender(N) | Time | UCMF-UC | GMV-UC | GMVF-UC |
|---|---|---|---|---|
| **Females** | | | | |
| 2020 | 3 months | -4.14 (-8.32, 0.02) | -4.03 (-8.02, -0.05) | -1.88 (-5.98, 2.2) |
| | 12 months | -3.34 (-7.51, 0.82) | -4 (-7.99, -0.03) | -4.65 (-8.75, -0.57) |
| **Males** | | | | |
| 870 | 3 months | -1.09 (-5.98, 3.8) | -1.07 (-5.86, 3.7) | 1.26 (-3.63, 6.13) |
| | 12 months | 0.18 (-4.72, 5.08) | -1.28 (-6.07, 3.49) | -1.93 (-6.81, 2.93) |

Table 10: Sub-group analysis for age

| Age group(N) | Time | UCMF-UC | GMV-UC | GMVF-UC |
|---|---|---|---|---|
| Age:35-45 years | | | | |
| 913 | 3 months | -3.18 (-7.9, 1.55) | -4.79 (-9.52, -0.08) | -1.04 (-5.89, 3.78) |
| | 12 months | -3.72 (-8.44, 1.02) | -5.62 (-10.34, -0.91) | -4 (-8.82, 0.81) |
| Age 55- 74 years | | | | |
| 1588 | 3 months | -3.75 (-8.12, 0.62) | -3.25 (-7.42, 0.89) | -0.1 (-4.37, 4.16) |
| | 12 months | -2.59 (-6.95, 1.78) | -2.79 (-6.95, 1.35) | -4.01 (-8.27, 0.24) |
| Age >=75 years | | | | |
| 389 | 3 months | -1.55 (-8.17, 5.06) | 0.57 (-5.68, 6.83) | -3.52 (-9.92, 2.85) |
| | 12 months | 2.67 (-3.9, 9.23) | 0.83 (-5.43, 7.09) | -1.8 (-8.22, 4.61) |

Table 11: Sub-group analysis for monthly earnings

| Baseline Monthly Earnings(N) | Time | UCMF-UC | GMV-UC | GMVF-UC |
|---|---|---|---|---|
| Not formally employed | | | | |
| 1865 | 3 months | -2.43 (-6.78, 1.93) | -3.07 (-7.29, 1.18) | 0.03 (-4.32, 4.34) |
| | 12 months | -3.23 (-7.58, 1.13) | -2.57 (-6.78, 1.68) | -4.61 (-8.95, -0.3) |
| Kshs <5,000 | | | | |
| 746 | 3 months | -4.8 (-10.39, 0.75) | -4.29 (-9.41, 0.81) | -2.89 (-8.12, 2.35) |
| | 12 months | 0.4 (-5.17, 5.92) | -2.84 (-7.97, 2.25) | -1.49 (-6.72, 3.74) |
| Kshs 5,000-10,000 | | | | |
| 138 | 3 months | -6.64 (-15.75, 2.47) | -5.28 (-15.15, 4.57) | -1.84 (-11.26, 7.58) |
| | 12 months | -0.85 (-9.73, 8.02) | -5.95 (-15.54, 3.61) | -2.73 (-11.78, 6.32) |
| Kshs >10,000 | | | | |
| 134 | 3 months | -6.63 (-15.89, 2.6) | 5.13 (-3.5, 13.75) | 1.49 (-7.76, 10.75) |
| | 12 months | -2.7 (-12.18, 6.77) | -0.12 (-8.86, 8.62) | 0.84 (-8.65, 10.33) |

Table 12: Sub-group analysis for occupation

| Occupation Status(N) | Time | UCMF-UC | GMV-UC | GMVF-UC |
|---|---|---|---|---|
| **Unemployed** | | | | |
| 1838 | 3 months | -2.29 (-6.65, 2.09) | -3.15 (-7.39, 1.12) | 0.2 (-4.16, 4.54) |
| | 12 months | -3.31 (-7.67, 1.07) | -2.52 (-6.75, 1.75) | -4.93 (-9.29, -0.6) |
| **Agribusiness** | | | | |
| 582 | 3 months | -2.73 (-9.14, 3.65) | -1.72 (-7.47, 4.01) | -1.05 (-6.87, 4.79) |
| | 12 months | 4.62 (-1.73, 10.95) | -0.94 (-6.68, 4.78) | 0.12 (-5.7, 5.95) |

Table 13: Sub-group analysis for NHIF (National Health Insurance Fund)

| NHIF Status(N) | Time | UCMF-UC | GMV-UC | GMVF-UC |
|---|---|---|---|---|
| **NHIF: No** | | | | |
| 2400 | 3 months | -3.38 (-7.47, 0.7) | -3.12 (-7.03, 0.79) | -1.3 (-5.33, 2.69) |
| | 12 months | -2.74 (-6.82, 1.34) | -3.34 (-7.25, 0.57) | -4.33 (-8.36, -0.35) |
| **NHIF: Yes** | | | | |
| 489 | 3 months | -2.77 (-8.4, 2.85) | -4.01 (-9.56, 1.49) | 0.17 (-5.44, 5.8) |
| | 12 months | -0.22 (-5.87, 5.41) | -3.1 (-8.62, 2.37) | -1.9 (-7.48, 3.7) |

## A.4 Transportability sub-group analysis

**Propensity score model fitted without baseline earnings and occupation**

Table 14: Sub-group analysis for gender

| Gender(N) | Time | UCMF-UC | GMV-UC | GMVF-UC |
|---|---|---|---|---|
| **Females** | | | | |
| 2020 | 3 months | -3.56 (-3.56, -3.49) | -6.29 (-6.29, -6.22) | -4.51 (-4.51, -4.44) |
| | 12 months | -3.9 (-3.9, -3.83) | -3.91 (-3.91, -3.85) | -2.36 (-2.36, -2.29) |
| **Males** | | | | |
| 870 | 3 months | 0.38 (0.38, 0.45) | 0.89 (0.89, 0.96) | 3.33 (3.33, 3.4) |
| | 12 months | -1.79 (-1.79, -1.72) | -1.98 (-1.98, -1.91) | -3.32 (-3.32, -3.25) |

Table 15: Sub-group analysis for age

| Age group(N) | Time | UCMF-UC | GMV-UC | GMVF-UC |
|---|---|---|---|---|
| Age:35-45 years | | | | |
| 913 | 3 months | -2.53 (-2.53, -2.45) | -5.99 (-5.99, -5.91) | -2.72 (-2.72, -2.64) |
| | 12 months | -4.43 (-4.43, -4.35) | -4.54 (-4.54, -4.46) | -2.26 (-2.26, -2.18) |
| Age 55- 74 years | | | | |
| 1588 | 3 months | -2.76 (-2.76, -2.68) | -2.47 (-2.47, -2.4) | -0.08 (-0.08, 0) |
| | 12 months | -2.59 (-2.59, -2.51) | -3.11 (-3.11, -3.04) | -3.21 (-3.21, -3.14) |
| Age >=75 years | | | | |
| 389 | 3 months | 1.82 (1.82, 1.95) | 2.39 (2.39, 2.52) | -1.15 (-1.16, -1.03) |
| | 12 months | -0.93 (-0.93, -0.8) | -2.14 (-2.14, -2.01) | -5.5 (-5.5, -5.37) |

Table 16: Sub-group analysis for monthly earnings

| Baseline Monthly Earnings(N) | Time | UCMF-UC | GMV-UC | GMVF-UC |
|---|---|---|---|---|
| Not formally employed | | | | |
| 1865 | 3 months | -1.33 (-1.33, -1.25) | -4.37 (-4.38, -4.29) | 1.37 (1.36, 1.45) |
| | 12 months | -4.13 (-4.13, -4.05) | -3.03 (-3.04, -2.95) | -4.97 (-4.97, -4.89) |
| Kshs <5,000 | | | | |
| 746 | 3 months | -3.28 (-3.28, -3.18) | -5.26 (-5.26, -5.17) | -6.19 (-6.2, -6.1) |
| | 12 months | 0.18 (0.18, 0.28) | -1.62 (-1.62, -1.53) | 1.37 (1.37, 1.46) |
| Kshs 5,000-10,000 | | | | |
| 138 | 3 months | -2.48 (-2.48, -2.33) | -0.07 (-0.07, 0.08) | 1.47 (1.46, 1.61) |
| | 12 months | -4.93 (-4.93, -4.78) | -8.12 (-8.12, -7.97) | -6.78 (-6.79, -6.63) |
| Kshs >10,000 | | | | |
| 134 | 3 months | -6.48 (-6.48, -6.33) | 7.12 (7.12, 7.25) | 4.74 (4.74, 4.88) |
| | 12 months | -1.39 (-1.39, -1.24) | 1.96 (1.96, 2.1) | -0.56 (-0.56, -0.41) |

Table 17: Sub-group analysis for occupation

| Occupation Status(N) | Time | UCMF-UC | GMV-UC | GMVF-UC |
|---|---|---|---|---|
| **Unemployed** | | | | |
| 1838 | 3 months | -1.1 (-1.1, -1.01) | -4.16 (-4.17, -4.08) | 1.57 (1.57, 1.66) |
| | 12 months | -4.22 (-4.22, -4.13) | -2.86 (-2.86, -2.77) | -5.16 (-5.16, -5.07) |
| **Agribusiness** | | | | |
| 1838 | 3 months | -0.61 (-0.61, -0.48) | -1.77 (-1.77, -1.66) | -2.82 (-2.82, -2.71) |
| | 12 months | 3.84 (3.84, 3.96) | -0.73 (-0.73, -0.62) | 1.17 (1.17, 1.28) |

Table 18: Sub-group analysis for NHIF (National Health Insurance Fund)

| NHIF Status(N) | Time | UCMF-UC | GMV-UC | GMVF-UC |
|---|---|---|---|---|
| **NHIF: No** | | | | |
| 2400 | 3 months | -2.17 (-2.17, -2.11) | -3.81 (-3.81, -3.75) | -1.91 (-1.91, -1.84) |
| | 12 months | -3.91 (-3.91, -3.84) | -3.86 (-3.86, -3.79) | -3.29 (-3.29, -3.23) |
| **NHIF: Yes** | | | | |
| 489 | 3 months | -1.95 (-1.95, -1.86) | -2.97 (-2.97, -2.89) | -0.03 (-0.03, 0.05) |
| | 12 months | -0.51 (-0.52, -0.43) | -2.59 (-2.59, -2.51) | -2.14 (-2.14, -2.06) |

## A.5 Multiple Imputation Results

Table 19: Multiple Imputation Results for BIGPIC study vs transportability analysis

| | BIGPIC Study | | | Target Population | | |
|---|---|---|---|---|---|---|
| | **UCMF-UC** | **GMV-UC** | **GMVMF-UC** | **UCMF-UC** | **GMV-UC** | **GMVMF-UC** |
| sbp change 3m | -3.38 (-7.89, 1.13) | -3.46 (-7.76, 0.84) | -1.64 (-6.06, 2.78) | -5.97 (-10.68, -1.26) | -6.88 (-11.40, -2.37) | -6.80 (-11.43, -2.17) |
| sbp change 12m | -2.32 (-6.83, 2.18) | -3.36 (-7.66, 0.94) | -4.01 (-8.43, 0.41) | 2.31 (-2.40, 7.03) | -1.30 (-5.82, 3.21) | 0.96 (-3.67, 5.59) |
| dbp change 3m | -3.30 (-5.17, -1.42) | -1.65 (-3.56, 0.27) | -1.50 (-3.44, 0.45) | -3.72 (-5.66, -1.78) | -1.67 (-3.64, 0.30) | -2.09 (-4.11, -0.07) |
| dbp change 12m | -2.29 (-4.17, -0.41) | -1.56 (-3.48, 0.35) | -3.15 (-5.10, -1.21) | -1.32 (-3.26, 0.62) | -2.04 (-4.02, -0.07) | -2.02 (-4.03, -0.00) |

Table 20: Weighted results for Multiple Imputation: Adjusting for Occupation

| | Adjusted Model | | | Unadjusted Model | | |
|---|---|---|---|---|---|---|
| | **UCMF-UC** | **GMV-UC** | **GMVMF-UC** | **UCMF-UC** | **GMV-UC** | **GMVMF-UC** |
| sbp change 3m | -5.48 (-10.06, -0.90) | -6.38 (-10.75, -2.01) | -6.59 (-11.08, -2.10) | -6.97 (-11.65, -2.28) | -6.03 (-10.72, -1.35) | -8.17 (-12.85, -3.49) |
| sbp change 12m | 1.76 (-2.82, 6.34) | -1.73 (-6.10, 2.64) | 1.06 (-3.43, 5.54) | 0.27 (-4.41, 4.95) | -1.38 (-6.07, 3.30) | -0.53 (-5.20, 4.15) |
| dbp change 3m | -3.94 (-5.86, -2.02) | -2.42 (-4.36, -0.47) | -2.70 (-4.68, -0.71) | -3.76 (-5.99, -1.53) | -2.66 (-4.88, -0.44) | -3.29 (-5.51, -1.07) |
| dbp change 12m | -1.16 (-3.08, 0.76) | -1.29 (-3.24, 0.65) | -1.27 (-3.26, 0.71) | -0.97 (-3.20, 1.25) | -1.54 (-3.76, 0.68) | -1.86 (-4.08, 0.36) |

Table 21: Weighted results for Multiple Imputation: Adjusting for Monthly earnings

| | Adjusted Model | | | Unadjusted Model | | |
|---|---|---|---|---|---|---|
| | **UCMF-UC** | **GMV-UC** | **GMVMF-UC** | **UCMF-UC** | **GMV-UC** | **GMVMF-UC** |
| sbp change 3m | -7.09 (-11.97, -2.21) | -4.66 (-9.35, 0.02) | -5.32 (-10.10, -0.54) | -8.52 (-13.43, -3.61) | -4.71 (-9.63, 0.21) | -6.84 (-11.74, -1.95) |
| sbp change 12m | 1.86 (-3.02, 6.74) | -2.83 (-7.51, 1.86) | -0.42 (-5.20, 4.36) | 0.44 (-4.48, 5.35) | -2.87 (-7.79, 2.04) | -1.94 (-6.84, 2.95) |
| dbp change 3m | -4.11 (-6.33, -1.89) | -0.79 (-3.05, 1.47) | -1.75 (-4.03, 0.53) | -4.02 (-6.36, -1.68) | -1.26 (-3.59, 1.07) | -2.48 (-4.80, -0.16) |
| dbp change 12m | -1.49 (-3.71, 0.72) | -2.75 (-5.01, -0.49) | -2.37 (-4.65, -0.08) | -1.40 (-3.74, 0.94) | -3.22 (-5.56, -0.89) | -3.09 (-5.42, -0.77) |

Table 22: Weighted results for Multiple Imputation: Adjusting for both Occupation and Monthly earnings

| | Adjusted Model | | | Unadjusted Model | | |
|---|---|---|---|---|---|---|
| | **UCMF-UC** | **GMV-UC** | **GMVMF-UC** | **UCMF-UC** | **GMV-UC** | **GMVMF-UC** |
| sbp change 3m | -2.81 (-7.42, 1.79) | -3.54 (-7.94, 0.86) | -2.96 (-7.48, 1.56) | -3.66 (-8.60, 1.29) | -3.75 (-8.71, 1.20) | -4.27 (-9.23, 0.69) |
| sbp change 12m | -2.86 (-7.46, 1.75) | -3.61 (-8.01, 0.79) | -2.92 (-7.44, 1.60) | -3.70 (-8.64, 1.24) | -3.83 (-8.78, 1.13) | -4.23 (-9.19, 0.73) |
| dbp change 3m | -3.25 (-5.16, -1.34) | -1.70 (-3.66, 0.26) | -1.86 (-3.85, 0.12) | -2.94 (-5.09, -0.78) | -2.02 (-4.19, 0.14) | -2.46 (-4.63, -0.30) |
| dbp change 12m | -2.71 (-4.61, -0.80) | -2.30 (-4.26, -0.34) | -2.91 (-4.90, -0.93) | -2.39 (-4.55, -0.24) | -2.62 (-4.79, -0.46) | -3.51 (-5.68, -1.35) |

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